Supreme Court, U.S.
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No.

In the Supreme Court of the United States

BAXTER INTERNATIONAL INC., BAXTER HEALTHCARE CORPORATION, BRISTOL-MYERS SQUIBB COMPANY, MINNESOTA MINING AND MANUFACTURING COMPANY AND UNION CARBIDE CORPORATION,

PETITIONERS,

v.

UNITED STATES OF AMERICA,

RESPONDENT.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the judgment of the Court of Appeals for the Eleventh Circuit must be reversed because the court adopted an erroneous interpretation of the term "self-insured plan" as used in the Medicare Secondary Payer statute, 42 U.S.C. § 1395y, in conflict with the ordinary meaning of that term and the interpretation adopted by the Second and Fifth Circuits.

2. Whether the judgment of the Court of Appeals for the Eleventh Circuit must be reversed because the court adopted an erroneous standard for determining the liability of pass-through payers of insurance proceeds in conflict with the interpretation of the Medicare Secondary Payer statute adopted by the D.C. Circuit.

RULE 29.6 STATEMENT

Petitioner Baxter International, Inc. does not have a parent corporation and no publicly held company owns 10% or more of Baxter International, Inc.'s stock.

The parent corporation of Baxter Healthcare Corporation is Baxter International, Inc. No publicly held company owns 10% or more of Baxter Healthcare Corporation's stock.

Petitioner Bristol-Myers Squibb Co. does not have a parent corporation and no publicly held company owns 10% or more of Bristol-Myers Squibb Co.'s stock.

Petitioner Minnesota Mining and Manufacturing Co. does not have a parent corporation and no publicly held company owns 10% or more of Minnesota Mining and Manufacturing Co.'s stock.

Petitioner Union Carbide Corp. is a wholly owned subsidiary of The Dow Chemical Co.

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The District Court's opinion (Pet. App. 71a-108a) is published at 174 F. Supp. 2d 1242. The Eleventh Circuit's opinion (Pet. App. 1a-70a) is published at 345 F.3d 866.

JURISDICTION

The Eleventh Circuit denied Petitioners' petition for rehearing on December 23, 2003. Pet. App. 110a-12a. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The Appendix reproduces the provisions of 42 U.S.C. § 1395y and the regulations involved in this case. Pet. App. 113a-48a.

STATEMENT OF THE CASE

This case concerns the proper interpretation of the Medicare Secondary Payer statute (MSP), a scheme that makes Medicare coverage secondary to other available insurance coverage, requiring those insurers to pay first ahead of Medicare. In this case, the United States sued Petitioners, defendants in the nationwide breast implant litigation, seeking reimbursement for Medicare payments allegedly made to women who participated in a more than $1 billion industry-wide settlement with Petitioners. The District Court concluded that the MSP was not designed to afford a remedy against insured tortfeasors that have settled claims with Medicare beneficiaries and dismissed the complaint for failure to state a claim. The Eleventh Circuit reversed in an unprecedented opinion that transforms tortfeasors who purchased insurance with deductibles into "self-insured plans," creating liability never before recognized and in conflict with the law of other circuits.

I. REGULATORY BACKGROUND

When Petitioners entered into their court-approved class settlement, there was no basis for the Government's reading of the MSP or its implementing regulations. In fact, the first courts addressing the issue chided the Government for its novel and aggressive position. *See In re Dow Corning*

Corp., 250 B.R. 298, 339 (Bankr. E.D. Mich. 2000) (Government's theory "add[ed] a new twist to the notion of strict liability" that "perhaps . . . would have some merit" in "the former Soviet Union"). The text, structure and history of the MSP all demonstrated that the obligations imposed by the MSP only extended to (1) insurers with an obligation to pay a Medicare beneficiary's medical bills under the terms of an insurance plan; and (2) the ultimate recipients of any such insurance payments. Petitioners do not fall within either category.

1. Under the MSP, Congress prioritized the responsibilities of various insurers for payment of healthcare costs.[1] Medicare will make payments for its beneficiaries but it will not be the primary insurer if another insurer is "required or responsible" to pay for the items or services under the terms of an insurance plan. *See* 42 U.S.C. § 1395y(b)(2)(B)(ii). The insurance programs subject to MSP obligations are referred to as "primary plans." *See id.* § 1395y(b)(2). "Primary plans" are defined to include group health plans as well as "liability insurance polic[ies] or plan[s]," including "self-insured plan[s]." *Id.* § 1395y(b)(2)(A). The MSP does not define a "self-insured liability insurance plan." But the Centers for Medicare and Medicaid Services (CMS)[2] regulations define a "self-insured plan" as a plan under which an entity "carries its own risk instead of taking out insurance with a carrier," and "liability insurance" as "insurance (including a self-insured plan) that provides payment based on legal liability for injury or illness or damage to property." 42 C.F.R. § 411.50.

When Medicare makes a payment and receives notice that payment "has been or could be made under" a primary

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[1] As set forth *infra*, the MSP has been amended. *See* Pet. App. 126a-38a (MSP post-December 2003). This section discusses the terms of the MSP as codified at the time of the decisions below. *See* Pet. App. 113a-25a.

[2] In 2001, the Healthcare Financing Administration (HCFA) was renamed the Centers for Medicare and Medicaid Service (CMS).

plan, then Medicare's payment is deemed conditional and subject to reimbursement. 42 U.S.C. § 1395y(b)(2)(B)(i). As the District Court explained, "[T]he United States may sue to recover conditional Medicare payments," Pet. App. 76a (citing 42 U.S.C. § 1395y(b)(2)(B)(ii)), but the MSP "names only two entities subject to suit by the United States" (Pet. App. 96a): the entity that "is required or responsible . . . to make payment with respect to such item or service . . . under a primary plan" or the entity "that has received payment . . . with respect to the item or service," such as a "physician or provider." 42 U.S.C. § 1395y(b)(2)(B)(ii). The MSP ensures that the Government's reimbursement rights are superior to those of any other subrogee of the beneficiary by providing that the Government "shall be subrogated (to the extent of payment made under this subchapter for such an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan." *Id.* § 1395y(b)(2)(B)(iii).

2. Congress unmistakably intended the MSP to authorize recovery from *insurers*, not insured tortfeasors. The legislative history to the 1980 amendments which extended the reach of the MSP from group health plans to liability insurance demonstrates that Congress intended to reach "private insurance carrier[s]," H.R. Rep. No. 97-1167, at 389 (1980), *reprinted in* 1980 U.S.C.C.A.N. 5526, 5752, and that "the insurance of the individual at fault" would be primary to Medicare, 126 Cong. Rec. 17,011 (1980). In 1989, Congress explained that in the case of liability insurance, providers bill Medicare first, and "Medicare subsequently recovers its costs from the liability insurer of the person who caused the injury." H.R. Conf. Rep. No. 101-386, Joint Explanatory Statement to the Omnibus Reconciliation Act of 1989, at 818-19 (1989), *reprinted in* 1989 U.S.C.C.A.N. 3018, 3421-22.

When Congress has set out to authorize recovery directly from tortfeasors, it has done so expressly and

unambiguously, as in the Medical Care Recovery Act (MCRA), 42 U.S.C. §§ 2651-2653. The MCRA grants the United States "under circumstances creating a tort liability upon some third person ... a right to recover ... the reasonable value of medical care" provided to or paid for by the United States. *Id.* § 2651(a). The MCRA grants the United States a subrogatory interest in the injured party's right to payment, *id.*, and enables the United States to sue *tortfeasors* by direct legal action or by intervening in an action brought by an injured party, *id.* § 2651(d).[3] By contrast, the MSP provides that *insurers*—including state insurers, private insurers, liability insurers, and "self-insured plans"—will pay before Medicare.

II. HISTORY OF PROCEEDINGS

1. On June 25, 1992, the Judicial Panel on Multidistrict Litigation transferred to Judge Sam C. Pointer, Jr., all pending federal court actions seeking damages for injuries allegedly resulting from silicone-gel breast implants manufactured primarily in the 1970s and 1980s. The Panel urged the parties "to work cooperatively with one another and with Judge Pointer toward the goal of a just, efficient and expeditious resolution of the litigation." *In re Silicone Gel Breast Implants Prods. Liab. Litig.*, 793 F. Supp. 1098, 1101 (J.P.M.L. 1992). In September 1994, the MDL Court certified a Rule 23(b)(3) opt-out settlement class, and issued a final judgment approving the settlement. *See* R.47 Ex. 10.

The court's orders sought to ensure that Petitioners would not be exposed to further liability and that the subrogation interests of CMS and other insurers would be protected. Judge Pointer made clear that a public healthcare provider could "pursue and perhaps intercept, in whole or in part, the benefits that may become payable to

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[3] The United States never asserted a claim against Petitioners under the MCRA. The United States did assert a claim under the MCRA against another party, *see* R.1, Gov't Compl. ¶¶ 80-91 (Pet. App. 163a-65a), but it did not appeal the district court's dismissal of those claims, Pet. App. 6a. ("R." refers to items from the district court record.)

individual members of the class." R.47 Ex. 10 (Pet. App. 167a). He also explained that the merits of any subrogation claim could not be determined before claims were processed because "these claims *necessarily depend upon a determination of the benefits payable to particular members of the class*," but emphasized that "[t]he court will consider these issues at a later time, before any distributions . . . are made." *Id.* (Pet. App. 168a) (emphasis added). The court then requested all insurers to file motions "that in some appropriate manner identify the persons on whose behalf subrogation claimants have paid medical expenses, rather than simply assert a general claim against the class." *Id.*

Response to the settlement was extraordinary. Over 400,000 women registered, overwhelming the amount of money available to pay them. In May 1995, Dow Corning, the settlement's largest contributor, filed a voluntary petition for reorganization, prompting extensive additional conferences to produce a revised settlement without Dow Corning. The Revised Settlement Program (RSP), approved by Judge Pointer in December 1995, is the result of these efforts. R.29 Ex. A., RSP. In the exercise of his equitable powers, Judge Pointer expressly determined that the RSP Defendants would be relieved of any "additional responsibilities" to private insurers and "governmental agencies" asserting claims "based on payment of medical expenses," because such claims will, "to the extent enforceable under applicable laws, be the responsibility of eligible participants." *Id.* at ¶ K.4 (Pet. App. 171a). At the same time, the court unquestionably preserved the opportunity for reimbursement of governmental entities and retained jurisdiction to resolve conflicting claims to settlement payments. *See supra* at 4-5; R.12 Ex. I ¶ 26 (Pet. App. 172a-73a).

Under the terms of the settlement, Petitioners had no way to know which claimants may have received any Medicare payments related to breast implants. First, Petitioners' contributions to the settlement had to occur in

advance of any benefits determinations. The RSP approval order required the three principal RSP Defendants (Baxter, Bristol-Myers Squibb, and 3M) to pay $375 million into the existing MDL 926 Settlement Fund. R.29 Ex. A, Revised Settlement Program ¶ J (Pet. App. 170a) This payment financed, among other things, future settlement payments that would be authorized by the Claims Office. *Id.*; R.29 Ex. B, Breast Implant Litig. Notice ¶¶ 28, 30(d), 31. Second, Petitioners had no responsibility for reviewing or approving claims. That function was reserved to a court-appointed Claims Office. Third, class members could establish eligibility for settlement payments without proof of any medical expenses. Thus, even the Claims Office would not have a need to know whether claimants incurred expenses paid for by Medicare or anyone else.

2. The Government participated in the settlement approval process. *See, e.g.*, R.12 Ex. G at 2; R.49 Ex. C at 372-74; R.12 Ex. J at 11. At no point during these months, however, did the Government ask the MDL Court, the Escrow Agent, or the Claims Office to implement any procedures to facilitate the identification of Medicare beneficiaries or to withhold payments to any class members who had received Medicare payments. Nor did the Government do so in 1997, as settlement payments continued to flow. The Claims Office established procedures for subrogees to intercept payments. Pet. App. 81a. Other insurers recovered Medical expenses through this process but the Government stood mute. The Government's failure to take any such specific steps is reviewed at some length in *In re Dow Corning Corp.*, 250 B.R. 298, 312-13 (Bankr. E.D. Mich. 2000), which indicates that in 1998, the bankruptcy court actually suggested to the Government that it approach Judge Pointer for this purpose. The Government still did not do so, and instead filed this action.

In its complaint filed in March 2000—nearly four years after the first settlement disbursements were made to claimants—the Government alleged that the RSP

Defendants were liable under the MSP for payments Medicare made on behalf of its beneficiaries. The Government advanced two theories of liability—that the RSP Defendants were liable as "primary payers" or as entities that "receive[d] payment" from a primary payer. Gov't Compl. ¶¶ 57-62, 63-65 (Pet. App. 160a, 161a).

According to the Government, the RSP Defendants were "self-insured" or "self-insured in part" "against the risk of products liability claims by breast implant recipients, and paid such claims from self-insured funds or retained earnings." *Id.* ¶¶ 43-44 (Pet. App. 157a-58a). In the alternative, the Government alleged that the RSP Defendants "purchased liability insurance against the risk of products liability litigation that covered, in whole or in part, the claims made by breast implant recipients," and "pa[id] with insurance proceeds, or cause[d] their insurers to pay," such claims. *Id.* ¶¶ 45-46 (Pet. App. 158a).

The Government alleged that the RSP Defendants were liable as primary payers because once they agreed to settle the class action, they were required to direct a portion of their settlement payments to Medicare instead of the RSP Fund.[4] *Id.* ¶¶ 37-42 (Pet. App. 156a-57a). Petitioners allegedly "did not ascertain" whether Medicare payments had been made on behalf of claimants and subsequently failed to notify CMS of such payments so that CMS could receive reimbursement. *Id.*[5] Due to this putative failure to

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[4] The Government did not allege that CMS would have any rights against Petitioners under the MSP but for the settlement. *See, e.g.*, Gov't Compl. ¶ 37 (Pet. App. 156a-57a).

[5] Under CMS regulations, however, a primary payer is only obligated to provide notice "[i]f [it] learns" that Medicare made a payment. 42 C.F.R. § 411.25. CMS has explained that the regulations do not impose a duty of inquiry because the regulation only applies where the primary payer "'has in its possession direct information that Medicare has made a conditional primary payment or information necessary to draw the conclusion that Medicare has made a conditional primary payment.'" *HIAA v. Shalala*, 23 F.3d 412, 418 (D.C. Cir. 1994) (quoting Declaration of Paul J. Olenick), *cert. denied*, 513 U.S. 1147 (1995).

comply with the MSP, the RSP Defendants were "required to pay the United States for conditional Medicare payments made on behalf of Claimants" for Medicare covered services. *Id.* ¶¶ 57-59 (Pet. App. 160a). The Government sought reimbursement of its Medicare payments notwithstanding the payments the RSP Defendants had already made through the settlement. Moreover, the Government also sued for double damages as a penalty. *Id.* ¶¶ 60-62 (Pet. App. 160a). In the alternative, the Government alleged that "the RSP Defendants received payments from product liability insurers or caused such payments to be made" and were therefore liable for damages as entities that "received payment." *Id.* ¶¶ 63-65 (Pet. App. 161a).[6]

III. DECISIONS BELOW

1. In a comprehensive decision, the late Judge Edwin Nelson, Judge Pointer's successor, held that the Complaint failed to state a claim under the MSP. The District Court explained that the MSP was "designed to lower Medicare costs by making Medicare coverage secondary to coverage provided by private insurance programs" (Pet. App. 76a) and did not apply to Petitioners.

First, the court held that the RSP Defendants are not "primary plans" under the MSP. Joining every court to have considered the issue,[7] the court concluded that the MSP was directed at insurance entities and rejected the Government's attempt to characterize the RSP

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[6] The Government also sued the Escrow Agent, alleging that as the person charged with making payments from the fund, the Escrow Agent failed to ascertain whether Medicare had made a payment on behalf of a beneficiary before paying claimants, and was therefore required to reimburse the United States for its previous payments. Gov't Compl. ¶¶ 47-49, 71-74 (Pet. App. 158a, 162a). The Government sought injunctive relief, *id.* ¶¶ 75-79 (Pet. App. 162a-63a), and also sued the Escrow Agent under the MCRA, *id.* ¶¶ 80-85 (Pet. App. 163a-64a).

[7] *See infra* pp. 12-13.

Defendants—each of which carried liability insurance—as self-insured plans under the statute. Pet. App. 82a-85a.[8]

Second, the District Court rejected the Government's arguments that the RSP Defendants could be liable as entities that "received payment" from third parties when the Complaint alleged that they passed the insurance payments on to claimants. The court concluded that the statutory language obviously refers to the ultimate recipient of the payment and that Congress did not intend to impose liability for Medicare's conditional payments on an entity that was merely a conduit for transmission of funds: "Such strict liability is extraordinary, and the argument that Congress imposed this kind of liability *sub silentio* is absurd." *Id.* at 98a.[9] The District Court accordingly dismissed the complaint with prejudice because the Government did not proffer any viable theory for amending the complaint.

2. The Eleventh Circuit reversed the dismissal of the action and remanded for further proceedings. Pet. App. 70a.[10] Although the Eleventh Circuit acknowledged that the RSP Defendants "had at least some liability [insurance] coverage" (*id.* at 5a), it nevertheless reasoned that the RSP Defendants could be "self-insured plan[s]" under the MSP to

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[8] Even assuming the RSP Defendants were primary plans, the Court rejected the Government's contention that the RSP Defendants could be liable to reimburse the Government in the absence of any knowledge of Government payments to Medicare beneficiaries. The Court also held that the RSP Defendants had no duty to undertake an investigation for the benefit of the Government to determine Medicare involvement in each case. Pet. App. 85a-90a. In addition, the Court dismissed the Government's punitive claim for double damages. *Id.* at 92a-94a.

[9] The court dismissed the Government's claim for declaratory and injunctive relief, concluding that the RSP Defendants have no duty to ensure that the Government is paid before the Escrow Agent makes payment to a claimant. Pet. App. 94a. The district court also dismissed the Government's claims against the Escrow Agent. *Id.* at 101a-106a.

[10] The Eleventh Circuit's holdings with respect to the RSP Defendants' liability for double payment and double damages under the MSP are not at issue in this petition. *See* Pet. App. 52a-64a.

the extent those insurance policies had any deductibles. This reasoning was pivotal to the court's conclusion that the RSP Defendants could be liable to the Government as both primary payers and entities that received payment from a primary plan.

The Court of Appeals began by reviewing the District Court's central holdings defining a "self-insured plan":

> (1) [T]hat a "'self-insured plan' connotes some type of formal arrangement . . ." (2) " . . . by which funds are set aside and accessed to cover future liabilities;" (3) "[P]ayments [by a tortfeasor], without more, [do not] constitute a 'plan' of self-insurance;" (4) "The mere absence of insurance purchased from a carrier does not necessarily constitute a 'plan' of self-insurance" (quoting 54 Fed. Reg. 41727 (Oct. 11, 1989)); and (5) "Payments of deductibles . . . do not constitute a 'plan' of self- insurance."

Pet. App. 42a-43a (quoting 174 F. Supp. 2d at 1254-55) (alterations in original). The Court of Appeals "agree[d] with the District Court as to the first, third, and fourth holdings, but not as to the second and fifth." *Id.* at 43a.

The Eleventh Circuit determined that the term self-insurance "has no precise legal meaning," and that "there was no basis . . . to conclude that the term unambiguously requires a set-aside of funds." Pet. App. 47a-48a. The court acknowledged that the Fifth Circuit had expressed approval of the District Court's interpretation in an opinion that "extensively discussed the meaning of a self-insured plan" and had concluded that "'a "primary plan" of "self-insurance" requires an entity's *ex ante* adoption, for itself, of an arrangement for (1) a source of funds, and (2) procedures for distributing those funds when claims are made against the entity.'" *Id.* at 48a-49a (quoting *Thompson v. Goetzmann*, 315 F.3d 457, 463 (5th Cir. 2002)). The Eleventh Circuit nevertheless "respectfully disagreed" with the Fifth Circuit's conclusion that "there cannot be a self-

insured plan absent a setting aside of the funds and formal procedures." Pet. App. 49a.[11]

The Court of Appeals also took issue with the District Court's conclusion that deductibles are not evidence of self-insurance. For support, the court afforded "particular significance," *id.* at 45a, to a regulatory definition of "liability insurance payment" that the Government did not even cite in its briefs on appeal. Under CMS definitions, 42 C.F.R. § 411.50, the term "self-insured plan" is expressly defined as an entity that "carries its own risk instead of taking out insurance with a carrier," and does not mention deductibles. Nevertheless, the Court of Appeals concluded that deductibles could constitute self-insurance because a different term—"liability insurance payment"—is defined to include deductibles. Pet. App. 45a, 47a. But the court reached this conclusion without examining the regulatory history or the fact that this term is used for the sole purpose of regulating Medicare price caps. And in marked contrast to the Fifth Circuit, which had refused to defer to the Government's construction of the MSP statute, *Thompson v. Goetzmann*, 337 F.3d 489, 501-02 (5th Cir. 2003), the court deferred to a regulation that was never cited by the Government on appeal, *see* Pet. App. 45a (liability insurance payment definition is of "particular significance"), 47a (District Court holding is "squarely inconsistent with regulation"), 51a (panel will "look to the regulations to which we owe deference")). The court concluded that the RSP Defendants could be liable as primary payers because the record indicated that they may have had a "combination of deductibles and insurance policies deemed by the regulations to constitute a self-insured plan." *Id.* at 51a-52a.

Turning to whether the RSP Defendants could be liable as "entities that receive[d] payment" under the MSP, the Court of Appeals again relied on the RSP Defendants'

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[11] The Government never contended that it did (or could) allege facts sufficient to satisfy the Fifth Circuit's interpretation of a self-insured plan.

alleged status as insurers. The court recognized that Congress identified a "physician or provider" as examples of liable entities that "received payment," and that the doctrine of *ejusdem generis* should restrict the type of liable entities to those similar to the enumerated examples. It reasoned that the regulations included "'a beneficiary, provider, supplier, physician, attorney, State agency or private insurer that has received a third party payment'" and that therefore the RSP Defendants could be "private insurer[s]" who "received payment." Pet. App. 65a (quoting 42 C.F.R. § 411.24(g)). In the court's view, the RSP Defendants could have "received payment" because "the RSP manufacturers paid into the settlement fund out of their own earnings, then submitted claims to their liability carriers for partial reimbursement . . . thus making it both a payer (to its insured) and a recipient (in relation to its re-insurer)." Pet. App. 68a. Relying on *HIAA v. Shalala*, 23 F.3d 412 (D.C. Cir. 1994), the court reasoned that the Escrow Agent was a mere pass-through payer who had no responsibility for determining who is eligible for payment or the amount of such payments, and thus held that the Escrow Agent could not be liable under the MSP, but nonetheless held that the RSP Defendants could be liable. Pet. App. 67a-68a.

IV. THE GOVERNMENT'S EFFORTS TO SECURE RETROACTIVE AMENDMENTS TO THE MSP

By the fall of 2003, in no fewer than nine decisions, courts had rejected the Government's "uniformly feckless" attempts to hold tortfeasors liable under the MSP, each concluding that the MSP is intended to reach insurers, not tortfeasors.[12] In reaction to these litigation losses, the

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12 *See Thompson v. Goetzmann*, 337 F.3d at 497; *see also Mason v. Am. Tobacco Co.*, 346 F.3d 36 (2d Cir. 2003); *Thompson v. Goetzmann*, 2001 WL 771012 (N.D. Tex. July 3, 2001), *aff'd*, 315 F.3d 457 (5th Cir. 2002), *superseded*, 337 F.3d 489 (5th Cir. 2003) (per curiam); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 202 F.R.D. 154 (E.D. Pa. 2001); *In re Diet Drugs Prods. Liab. Litig.*, 2001 WL 283163 (E.D. Pa. Mar. 21, 2001);

Department of Justice lobbied Congress for amendments to the MSP. These amendments were buried within the recently enacted, 415-page Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Pub. L. No. 108-173, 117 Stat. 2066 (2003). The vast majority of the provisions of the MMA—and the main focus for Congress, the media, and the public—were amendments to create Medicare prescription drug benefits and alter other beneficiary services. *See id.* But the MMA also effected a sea change in the MSP and the settled understanding of the meaning of a "self-insured plan."

The MMA changes the definition of "primary plan," 42 U.S.C. § 1395y(b)(2)(A)(ii), adding a clause that states:

> An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.

MMA, Pub. L. No. 108-173, § 301(b)(1), 117 Stat. at 2222. The Conference Committee Report explained that "[t]he list of primary plans for which conditional payment could be made would be clarified; an entity engaging in a business, trade, or profession would be deemed as having a self-insured plan if it carries its own risk." H.R. Conf. Rep. No. 108-391, at 572 (2003), *reprinted in* 2004 U.S.C.C.A.N. 1808, 1940. In addition, the MMA revised the "receive[d] payment" clause to state: "the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity." Pub. L. No. 108-173, § 301(b)(3), 117 Stat. at 2222.

Senators Graham and Harkin stated that the MSP amendments would "secure savings" that would offset the

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United States v. Baxter Int'l, Inc., 174 F. Supp. 2d 1242 (N.D. Ala. 2001); *United States v. Philip Morris Inc.*, 156 F. Supp. 2d 1 (D.D.C. 2001); *United States v. Philip Morris Inc.*, 116 F. Supp. 2d 131 (D.D.C. 2000); *In re Dow Corning Corp.*, 250 B.R. 298 (E.D. Mich. 2000).

increased costs of the new Medicare prescription drug plan. 149 Cong. Rec. S8,276 (daily ed. June 20, 2003) (statement of Sen. Graham); 149 Cong. Rec. S8,534 (daily ed. June 25, 2003) (statement of Sen. Harkin). Both Senators offered into the Record a letter by U.S. Assistant Attorney General William E. Moschella in support of the MSP amendments. 149 Cong. Rec. S8,276; 149 Cong. Rec. S8,535 (June 25, 2003) (statement of Sen. Harkin). The letter stated that the amendments would protect the Medicare fund

> by clarifying that Medicare must be reimbursed whenever another insurer's responsibility to pay has been established. *[MMA Section 301] is consistent with the litigation positions taken by this Department and [CMS] in numerous court cases.*... Section 301 makes clear that an entity will be deemed to have a "self-insured plan" if it carries its own risk, in whole or in part.... These provisions of Section 301 *will resolve contentious litigation and are designed to protect the fiscal integrity of the Medicare program.*

149 Cong. Rec. S8,276 (emphasis added). Thus, the Government intended these amendments to alter the outcome of pending MSP litigation.

To "secure savings" immediately, Congress made these amendments retroactive to over 20 years ago. The prior House and Senate versions only made one amendment retroactive.[13] Suddenly in Conference Committee, at which there was no opportunity for public comment, *see* H.R. Conf. Rep. No. 108-391, *reprinted in* 2004 U.S.C.C.A.N. 1808, the

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13 Both versions stated that the effective date of an amendment clarifying Medicare's ability to make conditional payments (H.R. 1, 108th Cong. § 301(a)(2)(B) (2003)), was retroactive to 1984. H.R. 2473, 108th Cong., § 301(a)(2) (2003); S. 1, 108th Cong. § 461(a)(2) (2003). All of the other amendments—including the amendment regarding "self-insured plans"—applied only prospectively. *See* H.R. 2473 at § 301(b); S. 1 at § 461(b).

amendments at issue here were made retroactive to the effective date of "section 953 of the Omnibus Reconciliation Act of 1980 (Public Law 96-499[])." Pub. L. No. 108-173, § 301(d)(2); 117 Stat. at 2222. The Department of Justice, the Conference Committee, and Senator Grassley (Chair of the Senate Finance Committee) carefully labeled the amendments as mere "clarifications" of existing MSP law, 149 Cong. Rec. S15,585 (daily ed. Nov. 22, 2003) (statement of Sen. Grassley); H.R. Conf. Rep. No. 108-391, at 571, *reprinted in* 2004 U.S.C.C.A.N. at 1940; 149 Cong. Rec. S8,276, although the litany of defeats in MSP litigation across the country surely indicate that these amendments could alter drastically a tortfeasor's liability under the MSP.

REASONS FOR GRANTING THE WRIT

This case presents this Court with an opportunity to resolve an important conflict among the courts of appeals on the proper interpretation of the MSP and what constitutes insurance. *First*, the Eleventh Circuit's expansive definition of a "self-insured plan" for "liability insurance"—including the holding that deductibles may constitute such a plan—squarely conflicts with decisions of the Fifth and Second Circuits. *See* Pet. App. 42a-52a; *Mason v. Am. Tobacco Co.*, 346 F.3d 36, 40 (2d Cir. 2003) (rejecting the view that retaining "'any portion of . . . risk, no matter how small,'" can constitute a "self-insurance plan" (citation omitted)); *Thompson*, 337 F.3d at 498 (holding that to be a self-insured plan an entity must set aside funds and establish formal procedures for payment of claims in advance). Indeed, the Third Circuit recently acknowledged the conflict. *See Fanning v. United States*, 346 F.3d 386, 400 n.13 (3d Cir. 2003) ("[T]he government's argument that a 'self-insured plan' includes a fund created by a tortfeasor to settle litigation has engendered a circuit split. The Fifth Circuit . . . rejected the government's argument, while the Eleventh Circuit . . . accepted it."). *Second*, the Eleventh Circuit's holding that the RSP Defendants could be liable under the MSP as entities that "received payment" conflicts with the

D.C. Circuit's decision in *HIAA v. Shalala*, 23 F.3d 412 (D.C. Cir. 1994), that mere pass-through payers like the RSP Defendants are not liable under the MSP.

The MSP has been amended but the need for review persists. The proper interpretation of the statutory provisions at issue here will still have to be addressed in order to resolve the MSP liability of Petitioners and thousands of litigants across the country who have entered into settlements with or obtained judgments against alleged tortfeasors prior to December of 2003. As the facts of this case readily illustrate, parties subjected to retroactive imposition of liability under the MSP have a strong basis for a constitutional challenge. Here, the amendments purport to alter the rules of liability that governed in 1994 when the RSP Defendants committed to make more than $1 billion in settlement payments on terms approved by a federal district court. And the threshold issue in a constitutional challenge will necessarily be the meaning of the MSP prior to the 2003 amendments.

Nor is there any reason to defer review of the conflict pending the resolution of remand proceedings in this case. Under the law of the case doctrine, the RSP Defendants will be barred from arguing that any retroactive imposition of liability is unconstitutional because the District Court will be obligated to follow the Eleventh Circuit's construction of the MSP pre-amendment. Thus, Petitioners' constitutional challenge will necessarily fail. By contrast, similarly situated individuals in the Fifth and Second Circuits will be free to challenge the retroactivity of the MSP amendments, and enforce the proper construction of the term "self-insured plan" that is the law in those circuits. Accordingly, this Court's intervention is still needed to resolve this important conflict among the courts of appeals.

I. THE ELEVENTH CIRCUIT'S ERRONEOUS INTERPRETATION OF THE MSP SQUARELY CONFLICTS WITH THE DECISIONS OF OTHER CIRCUITS

A. Petitioners Were Entitled to Dismissal of This Action Under the Construction of "Self-Insured Plan" Adopted by the Fifth and Second Circuits

Under the MSP, the RSP Defendants can be liable as primary payers only if they were obligated to make the payments under the terms of a "self-insured plan," 42 U.S.C. § 1395y(b)(2)(A)—a "plan under which an individual ... carries its own risk *instead of taking out insurance with a carrier*," 42 C.F.R. § 411.50(b) (emphasis added). In *Goetzmann*, the Fifth Circuit dismissed with prejudice under Fed. R. Civ. P. 12(b)(6) the Government's MSP complaint against a manufacturer that settled a products liability claim. The record and express reasoning in *Goetzmann* leave no doubt that the Government's complaint against the RSP Defendants would have been dismissed under the legal standards applied by the Fifth Circuit.

In its complaint in *Goetzmann*, No. 02-10198, the Government alleged that "Zimmer was self-insured for its liability to Loftin," a Medicare beneficiary. *Goetzmann* Compl. ¶ 45; *see also* 337 F.3d at 493. The record in *Goetzmann* demonstrated that Zimmer had elected not to purchase product liability insurance, but the complaint did not allege that Zimmer had set aside a fund or established procedures for paying claims. *See* 337 F.3d at 500-01; *see also Goetzmann* Compl. The Fifth Circuit squarely held that the Government's claim accordingly failed as a matter of law. The court explained that a manufacturer that pays settlements entirely out of its own funds does not thereby maintain a "self-insured plan" for "liability insurance," and rejected the latest of the Government's "uniformly feckless" attempts to hold tortfeasors liable under the MSP. 337 F.3d at 497-98, 495. The court held that "in the sense used in the

MSP statute, a 'primary plan' of 'self-insurance' requires an entity's *ex ante* adoption, for itself, of an arrangement for (1) a source of funds and (2) procedures for disbursing these funds when claims are made against the entity." *Id.* at 498. The Fifth Circuit expressly relied on the District Court's decision in this case, quoting the court's conclusion that "'the regulatory language defining "self-insured plan" connotes some type of formal arrangement by which funds are set aside and accessed to cover future liabilities.'" *Id.* at 499 n.26 (quoting 174 F. Supp. 2d at 1254).[14]

The disposition of *Goetzmann* therefore unmistakably rests on the Fifth Circuit's interpretation of the term self-insured plan.[15] And in reversing the District Court's conclusion that a plan requires "funds [to be] set aside and accessed to cover future liabilities," the Eleventh Circuit squarely rejected the Fifth Circuit's holding. Recognizing as much, the Eleventh Circuit attempted to dismiss the Fifth Circuit's analysis as "dicta," and limit *Goetzmann* to its facts. *See* Pet. App. 49a ("respectfully disagree[ing] with

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14 The Fifth Circuit also noted that 42 C.F.R. § 411.21, which defines a "plan" of insurance, "contemplates a pre-arrangement and makes sense only if a self-insurer creates or maintains a fund or source and establishes rules for making disbursements therefrom in covering the self-insurer's future risk, *i.e.*, when one acts as an insurance carrier for oneself." 337 F.3d at 498-99.

15 The Fifth Circuit originally held that the complaint should be dismissed because (1) the Government could not prove that Zimmer was a self-insured plan; and (2) the complaint rested on a misinterpretation of the term "prompt payment" in the MSP. After its initial panel decision, 315 F.3d 457, the Government filed a petition for rehearing en banc and a petition for panel rehearing, urging the Fifth Circuit to revisit its construction of the "prompt payment" clause in the statute and its definition of a "self-insured plan." The Government even sought an opportunity to conduct discovery on the self-insurance issue. Pet. for Panel Reh'g at 13, *Thompson v. Goetzmann*, 337 F.3d 489 (5th Cir. 2003) (No. 02-10198). In its superseding opinion, 337 F.3d 489, the Fifth Circuit did withdraw its ruling on prompt payment, but held fast to its "self-insured plan" analysis, and affirmed the dismissal of the Government's complaint with prejudice notwithstanding the lack of discovery on that issue.

the *Goetzmann* dicta to the effect that there cannot be a self-insured plan absent a setting aside of the funds and formal procedures"). But simply saying the Fifth Circuit's analysis is dicta does not make it so, as the Third Circuit clearly recognized, *see Fanning*, 346 F.3d at 400 n.13, and the Fifth Circuit itself confirmed, *see* 337 F.3d at 497 ("The term 'primary plan' is pivotal to the applicability of the MSP statute."); *see also Seminole Tribe v. Florida*, 517 U.S. 44, 67 (1996) (explaining that the exclusive basis for a judgment is not dicta: "[w]hen an opinion issues for the Court, it is not only the result but also those portions of the opinion necessary to that result by which we are bound").

The Eleventh Circuit's decision also conflicts with an MSP decision of the Second Circuit. In *Mason*, Medicare beneficiaries sued several tobacco companies alleging that the companies were "self-insured" and, therefore, were the primary payers for healthcare services needed to treat tobacco-related illnesses. 346 F.3d at 37-38. The Second Circuit affirmed the dismissal of the complaint, rejecting the plaintiffs' construction of "self-insured plan":

> "Its logical implication is that any [corporate] entity with a risk of legal liability which chooses to retain *any portion of that risk, no matter how small*, may be pursued under MSP on the ground that it is a 'self-insured plan.' . . . [This] would transform the statute, meant primarily for use against insurers, into the very 'across-the-board procedural vehicle for suing tortfeasors,' which this Court has already declared impermissible."

Id. at 40 (citations omitted) (first alteration in original) (emphasis added).[16]

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[16] The Second Circuit noted, however, that this case could be distinguished because the RSP Defendants "had assumed obligations to pay." 346 F.3d at 42. That distinction might merit weight if the RSP (under which the RSP Defendants agreed to make payments) were itself the "plan" of self-insurance. Not so on this record. The United States

The Eleventh Circuit's analysis presents an even greater risk of transforming the MSP into an "across-the-board ... vehicle for suing tortfeasors" because virtually *every* insured tortfeasor carries deductibles. *See* 345 F.3d at 894-96 & n.20, 898 n.25. Thus, it is unsurprising that "courts have rejected all efforts to apply the statute's heavy remedy of double damages to the context of tort litigation" with "the exception of the Eleventh Circuit in its decision [here]." *Mason*, 346 F.3d at 42.

The Eleventh Circuit's holding that deductibles may constitute self-insurance also squarely conflicts with *Goetzmann* because the Fifth Circuit held that the ordinary and "unambiguous" meaning of the terms "plan" and "self-insured" required an *ex ante* adoption of a source of funds and procedures for disbursement. *See* 337 F.3d at 497-98 (citing Webster's Ninth New Collegiate Dictionary (1985) and 3 *Couch on Insurance* (3d 2000)).[17] In contrast, the Eleventh Circuit concluded that the term was ambiguous and held that the mere existence of a policy deductible could constitute self-insurance by affording *Chevron* deference to an inapposite regulation that the Government did not even cite in its appellate briefs.

The Eleventh Circuit concluded that the District Court's reasoning was "squarely inconsistent" with 42 C.F.R. § 411.50 because that regulation defines "liability insurance payments" to include "a payment to cover a deductible required by a liability insurance policy." *See* Pet. App. 47a.

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expressly disavowed any argument that the RSP itself is a "plan." *See* Pet. App. 83a & n.11 (district court opinion citing the Government's "Notice of Correction" (R.41) "in which it requested deletion of its contention that the RSP and other opt-out settlements were primary plans").

[17] In examining relevant authority, the Eleventh Circuit unearthed similar definitions of "self-insured plan" and even conceded that under these definitions a set-aside of funds would be expected. Pet. App. 43a. The court then inexplicably turned to inapposite cases that largely dealt with tax issues in adopting the panel's "more elastic" and expansive definition of that statutory term. *See id.* at 43a-44a.

But the text of the definition of liability insurance payment that the panel found "particular[ly] significan[t]" actually undercuts the court's conclusion. The definition expressly distinguishes between "a payment to cover a deductible required by a liability insurance policy" and a payment by any entity "covered by a self-insured plan" (42 C.F.R. § 411.50(b))—a distinction that makes no sense if deductible payments are part and parcel of a "self-insured plan." 345 F.3d at 894 & n.20.

Moreover, the sole use of the term "liability insurance payment" in CMS regulations is directed at a completely different issue: the agency's interest in enforcing Medicare's "limitation[s] on charges" imposed on healthcare providers "when a beneficiary has received a liability insurance payment." 42 C.F.R. § 411.54. CMS observed in its 1988 Notice of Proposed Rulemaking and the 1989 Final Rule that the then-current regulation failed adequately to prevent providers from placing liens on payments a Medicare beneficiary might receive.[18]

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[18] Medicare imposed price caps on covered services and tried to ensure that a provider could not circumvent those caps when a beneficiary received a "liability insurance payment." *See* 54 Fed. Reg. 41,716, 41,725-26 (Oct. 11, 1989); *see also* 53 Fed. Reg. 22,335, 22,339 (June 15, 1988) (noting that current regulations "Do not specify that *payments made by an insured party to cover deductibles imposed by the liability insurance policy* are considered to be liability insurance payments. . . . Do not clearly state that a provider has no right to charge a liability insurer or a beneficiary who has received a liability insurance payment. . . .") (emphasis added). The agency accordingly specified that "payments made *by an insured party to cover deductibles* imposed by the liability insurance company are considered to be *liability insurance payments*" in an effort to prevent a provider from recovering amounts in excess of the Medicare price cap by placing a lien on a tortfeasor's payment of a deductible to the beneficiary. 54 Fed. Reg. at 41,725 (emphasis added). Another court has rejected an attempt to resort to this unrelated regulatory provision in expanding the definition of a self-insured plan: "[T]hese regulations, because they apply in a different context for reasons specific to that context, have nothing to do with the MSPS, for which there already exists regulations defining a self-insured plan. Given this, it is neither necessary nor appropriate to resort to these unrelated HCFA

It is telling that the Government never even cited the liability insurance payment definition on appeal—an omission that was obviously intentional. The provision of the regulation that actually defines a "self-insured plan" makes no mention of deductibles; and logically so. *See* 42 C.F.R. § 411.50. While deductibles are evidence that an entity is insured, CMS defined a "self-insured plan" as "a plan under which an individual ... carries its own risk *instead* of taking out insurance with a carrier." *Id.* (emphasis added). *No* regulation purports to define policy deductibles as "self-insured plans," and rightly so because to conclude otherwise would impermissibly deprive the term of its ordinary meaning.

Indeed, to take one example, the Minnesota Supreme Court recently held that RSP Defendant Minnesota Mining and Manufacturing Company *did not* self-insure against the risk of breast implant-related liability. *See In re Silicone Implant Ins. Coverage Litig.*, 667 N.W.2d 405, 410 (Minn. 2003) (reciting trial court findings that 3M was not "self-insured" and "'sought to transfer its product liability risks to the maximum extent reasonably possible'"). The Eleventh Circuit's decision to equate deductibles with insurance squarely contradicts the ordinary meaning of a "self-insured plan" for "liability insurance" and conflicts with the decisions of other courts of appeals.

B. The Eleventh Circuit's "Receive[d] Payment" Analysis Conflicts With the D.C. Circuit

Under the Eleventh Circuit's logic, the RSP Defendants' payment of deductibles would make them self-insured, and thereby render them potentially liable as "private insurers" that "receive[d] payment" when they were reimbursed by their liability insurance carriers. Pet. App. at 51a-52a, 68a. Because the Eleventh Circuit's "received payment" analysis turns on whether the RSP Defendants were insurers, it

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regulations in applying the MSPS." *Brown v. Thompson*, 252 F. Supp. 2d 312, 320 n.10 (E.D. Va. 2003) (citation omitted).

warrants review for the same reasons outlined in the preceding section.[19]

In addition, the Eleventh Circuit's analysis conflicts with the D.C. Circuit's construction of the MSP in *HIAA v. Shalala*, 23 F.3d 412 (D.C. Cir. 1994). In *HIAA*, the Government argued that it had the right to seek recovery of conditional payments by "proceed[ing] directly against administrators" that issued payments on behalf of an insurer because it would be "impracticable" to sue the insurer instead of the pass-through payer. *Id.* at 416-17. The D.C. Circuit rejected the Government's "sketchy" and "jumble[d]" argument "for reading the MSP statute to authorize recovery actions against administrators that assume no financial responsibility for paying a plan's benefits." *Id.*[20] In the D.C. Circuit's view, the Government must sue the insurer directly. But the Eleventh Circuit reached the opposite conclusion and authorized MSP recovery actions against insured tortfeasors with deductibles that pass through insurance payments.

As the Eleventh Circuit recognized, even after congressional amendments in the wake of *HIAA*,[21] an entity

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[19] The Government never even argued the theory adopted by the Eleventh Circuit. The RSP Defendants obviously could not have received reimbursement for any payments made in their capacity as "private insurers" because a "self-insured" payment—by definition—would be one that an RSP Defendant made under a plan to "carr[y] its own risk instead of taking out insurance with a carrier." 42 C.F.R. § 411.50.

[20] The D.C. Circuit likened the situation to a bank that may receive funds and pay funds to a Medicare beneficiary; the role of receiving and making payment does not thereby render the bank a party that is responsible to pay within the meaning of the MSP. 23 F.3d at 416.

[21] In response to *HIAA*, Congress issued clarifying amendments to the MSP. *See* Balanced Budget Act of 1997, Pub. L. No. 105-33, §§ 4632-4633, 111 Stat. 251, 486-87 (Aug. 5, 1997). Congress made clear that the United States could recover against a third-party administrator of a plan only if that administrator was employed by the employer or group health plan responsible for payment and would be able to recover that payment from the employer or group health plan. *See* 42 U.S.C. § 1395y(b)(2)(B)(ii). Congress did not make pass through entities that

that is not responsible for making payment as an employee of the primary plan, and is merely a pass-through payer who does not "receiv[e] payment under a claim of right or entitlement to retain it," is not liable under the MSP. Pet. App. 65a. The Eleventh Circuit accordingly recognized that the Escrow Agent therefore could not be liable under the MSP. It nevertheless attempted to distinguish the RSP Defendants on the theory that the third-party administrator in *HIAA*, like the Escrow Agent, had no involvement in payment decisions. But that distinction fails. In *HIAA* the D.C. Circuit recognized that third-party administrators often were in the position to determine whom would get paid and the amount of payment, much like the Claims Office in this case. *Compare* 23 F.3d at 415 *with* Pet. App. 65a. In *HIAA* it was not the lack of discretion to determine eligibility and set payment that prevented MSP liability, but rather the status as a pass-through entity that was not financially responsible for payment "under the terms of the primary plan." And the D.C. Circuit's reading of the MSP would have been dispositive here because the Government has never even contended that the RSP Defendants were financially responsible for making payments owed under their insurance policies.

The Eleventh Circuit apparently believed that the inclusion of "insurers" in the list of parties who may "receive payment" under 42 C.F.R. § 411.24(g) necessarily meant that a tortfeasor that was a self-insured plan could be liable if the Government could prove it was a pass-through payer of insurance proceeds from its reinsurer. 345 F.3d at 908. But the panel misapprehended how "private insurer[s]" could be liable as entities that "receive[d] payment" under the MSP. The regulation reaches an insurer, such as a private health insurer, that provides coverage on behalf of a Medicare beneficiary, becomes a subrogee of the

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merely handled funds liable under the MSP or add any terms intended to reach insured tortfeasors.

beneficiary,[22] and later receives reimbursement from an *additional source* of insurance available to the beneficiary, such as a liability insurer. In that situation, the insurer has "receive[d] payment under a claim of right or entitlement to retain it" because it was a subrogee of the beneficiary. But the MSP does not allow the insurer to retain that payment if the Government has not first been reimbursed. The Government can recover from that "private insurer," 42 C.F.R. § 411.24(g), (or the physician or provider) because that health insurer is the ultimate recipient of a *second* primary payment that the Government has a right to reclaim because its subrogatory rights have priority. *See, e.g., Blue Cross & Blue Shield of Tex., Inc. v. Shalala*, 995 F.2d 70, 73 (5th Cir. 1993) (the MSP "dictate[s] the order of payment when Medicare beneficiaries already have alternate sources of payment for health care").

By contrast, a tortfeasor (even a self-insured plan) that passes funds originating from its (re)insurance carrier is not subject to "received payment" liability because it receives payment pursuant to a contract of insurance, *not* as a subrogee of the beneficiary. Thus, nothing in the MSP, its regulations, or the law of subrogation gives the Government a right to intercept reimbursement to the RSP Defendants from their insurers for payments they have made into the RSP. The Government's own allegations establish that the RSP Defendants are mere pass-through entities and the Government's claims would have been dismissed under the standards applied by the D.C. Circuit in *HIAA*.

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22 When receiving coverage or services, individuals commonly confer subrogation rights to private insurers or physicians that allow those parties to seek recovery from the party responsible for the condition that gave rise to the need for those benefits. *See Am. Cyanamid Co. v. United States Fid. & Guar. Co.*, 459 So. 2d 851, 853-54 (Ala. 1984) ("When one, under a claim of right, discharges an obligation for which another should be held legally liable for payment, then the former stands in the shoes of the obligor and may seek reimbursement against the latter for the damages caused by its allegedly culpable conduct.").

II. THE PROPER INTERPRETATION OF THE MSP PRESENTS AN ISSUE OF CONTINUING IMPORTANCE TO THOUSANDS OF ENTITIES AND INDIVIDUALS WHO HAVE ALLEGEDLY VIOLATED PAYMENT OBLIGATIONS TO THE GOVERNMENT

In response to the resounding rejection of the Government's construction of the MSP in litigation across the country, the Government secured retroactive amendments to the MSP in an effort to undermine the statutory interpretation of "primary plan" adopted by those courts. That legislative initiative, along with the Eleventh Circuit's anomalous decision, has unsettled the expectations of thousands who are either Medicare beneficiaries or tortfeasors who have paid settlements or judgments to Medicare beneficiaries. As the Fifth Circuit noted in *Goetzmann*, "[t]he term 'primary plan' is pivotal to the applicability of the MSP statute." 337 F.3d at 497.

In the breast implant class action settlement alone, a class numbering in the hundreds of thousands is unsettled as to obligations for Medicare reimbursement or for indemnification of the RSP Defendants.[23] In *Fanning v. United States*, approximately 1,800 settlement class members faced with Medicare reimbursement obligations related to orthopedic bone screws are actively seeking a resolution of the same issue presented by this petition. 346 F.3d 386, 390, 402 n.17 (3d Cir. 2003) (noting Government demand letters sent to 1,800 class members were "more suggestive of tactics one might attribute to a less than reputable collection agency rather than to one's own government"). As the Third Circuit explained, the reimbursement obligations of the class members are "wholly dependent upon determining whether or not [the settling tortfeasor] is a 'self-insured plan' . . . under the MSP." *Id.* at 400. Although the Third Circuit recognized that "there may

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[23] The RSP Defendants will have to join all class members who are Medicare beneficiaries in the remand proceedings in order to seek recovery of the original settlement payments.

be force to Fanning's [MSP] argument,"[24] *id.* at 399, it dismissed the case based on the conclusion that each class member would have to raise the issue through administrative remedies that had not been exhausted. In the *Diet Drugs* 1999 class action settlement, the court set aside a $7,000,000 reserve fund in case the Government ever proved its asserted MSP claims. *In re Diet Drugs Prods. Liab. Litig.*, 2001 WL 283163, at *12 (E.D. Pa. Mar. 21, 2001). In the Ninth Circuit, a class of Medicare beneficiaries awaits individual CMS determinations of whether settlements and judgments they secured from alleged tortfeasors are subject to MSP reimbursement. *Nygren v. United States*, 268 F. Supp. 2d 1275 (W.D. Wash. 2003).[25] Emboldened by the 2003 MSP amendments, only the Government knows how may additional MSP reimbursement demands it will make based upon events occurring from 1980 to 2003.

The Government labels the MSP amendments as mere "clarifications," but this label does not fit—these amendments change the MSP law. Given the changes to the standards that govern liability, the RSP Defendants will argue on remand that any retroactive imposition of the

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[24] The district court had enjoined the Government from recovering payments from the class on the grounds that the Government could not prove that the manufacturers constituted a "self-insured" plan. 202 F.R.D. 154, 164-67 (E.D. Pa. 2001).

[25] *See also, e.g., Penoyer v. United States*, 2004 WL 437461 (N.D.N.Y. Feb. 3, 2004) (Medicare beneficiary claims that MSP reimbursement is not required in medical malpractice settlements obtained by him and all similarly situated persons); *Wilson v. United States*, 58 Fed. Cl. 760 (2003) (Medicare beneficiary claims tort settlement is not subject to MSP reimbursement); *Maresh v. Thompson*, 290 F. Supp. 2d 737 (N.D. Tex. 2003) (same); *Baughan v. Thompson*, 2003 WL 22295354 (W.D. Va. Sept. 30, 2003) (same); *Bird v. Thompson*, 2003 WL 21537748 (S.D.N.Y. July 8, 2003) (same); *see also Manning v. Utils. Mut. Ins. Co.*, 2004 WL 235256 (S.D.N.Y. Feb. 9, 2004) (citing *Goetzmann*, holds employer who purchases workers' compensation coverage is not a "primary plan"); *Truett v. Bowman*, 288 F. Supp. 2d 909 (W.D. Tenn. 2003) (dismissing for failure to exhaust administrative remedies parties' attempt to join CMS in tort litigation to determine CMS's MSP reimbursement rights).

amendments would be unconstitutional. Indeed, this Court has repeatedly confirmed that the Constitution protects parties from state action that unjustly deprives them of property or a vested expectation of their rights and responsibilities. *See, e.g., E. Enters. v. Apfel*, 524 U.S. 498 (1998) (Takings Clause and Due Process Clause challenge); *Webb's Fabulous Pharmacies, Inc. v. Beckwith*, 449 U.S. 155 (1980) (Takings Clause challenge); *Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234 (1978) (Contracts Clause challenge).

In *Eastern Enterprises*, for example, five members of the Court invalidated Congress's attempt through retroactive legislation to alter settled expectations in the coal industry concerning the funding of health care benefits for retired coal miners and their dependents. The plurality explained that the constitutionality of the federal statute would be determined by its "justness and fairness," in view of "'the economic impact of the regulation, its interference with reasonable investment backed expectations, and the character of the governmental action.'" 524 U.S. at 523-24 (citation omitted). The plurality concluded that unlike other cases, where for instance an employer voluntarily created a pension plan covered by ERISA and could later expect to be heavily regulated, even by retroactive legislation, Eastern had long ago exited the coal industry but was later made subject to legislation that "reache[d] back 30 to 50 years to impose liability . . . [and] 'attach[] new legal consequences to [actions] completed before its enactment.'" *Id.* at 532 (citation omitted).[26]

Here, the 2003 MSP amendments impose a severe, disproportionate, and extremely retroactive burden on

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26 Justice Kennedy, who provided the fifth vote to invalidate the retroactive legislation, explained that the inquiry was whether the legislature acted in "an arbitrary and irrational way," 524 U.S. at 547, "chang[ing] the legal consequences of transactions long closed," and "destroy[ing] the reasonable certainty and security which are the very objects of property ownership," *id.* at 548.

alleged tortfeasors. The RSP Defendants have all long since ceased involvement with breast implants, and exited the industry. Moreover, the ailments and symptoms for which claimants have sought and received payment under the RSP tend to involve long latency periods, meaning that in many instances, claims are based upon events that occurred several years ago. Most importantly, the MDL Court endeavored in 1994 to achieve a fair and final resolution of all potential claims against the RSP Defendants in exchange for their willingness to abandon meritorious arguments on causation. Thus the MSP amendments, with a more than 20-year period of retroactivity, affect an unexpected upheaval of settled events, imposing novel responsibilities and unforeseen liability to make payment to the United States.[27]

Petitioners do not seek to argue the merits of a constitutional challenge to the retroactive MSP amendments at this stage, but rather to explain that the merits of this challenge will turn on the proper interpretation of the MSP pre-amendment and will be foreclosed by the law of the case doctrine absent this Court's review. The "justness and fairness" of the MSP amendments depend on the proper interpretation of that statute before the amendments occurred. Indeed, the first step of retroactivity analysis is to determine what the law previously required, before turning to analyze whether that law has been changed in violation of the Constitution. *United States v. Carlton*, 512 U.S. 26, 31 (1994) (construing

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[27] Unlike an employer that voluntarily creates a pension plan for its employees, the RSP Defendants, sued for injuries allegedly caused by breast implants, simply decided to settle these actions, and by that conduct the government now alleges the RSP Defendants became insurers. The RSP Defendants could not have foreseen that they would be converted into insurers by fiat. Although the insurance industry is highly regulated, no potential tortfeasor has reason to believe it might be labeled an insurer. And unlike *Eastern Enterprises*, the legislation at issue here results in payment to the Government, not to another private party. As Justice Kennedy noted, "the Government's self-enrichment may make it all the more evident a taking has occurred." 524 U.S. at 544.

meaning of 1986 statute before evaluating due process challenge to 1987 amendment). But in this case the first step of that analysis will end the inquiry because the court on remand will feel bound by the Eleventh Circuit's self-insured plan analysis under the law of the case doctrine. *See Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 816 (1988) (doctrine of law of the case "'posits that when a court decides upon a rule of law, that decision should continue to govern the same issues in subsequent stages of the same case'") (citation omitted).[28]

To be sure, the law of the case doctrine does not deprive this Court of jurisdiction, but here, where the retroactivity question will be mooted by the Eleventh Circuit's controlling interpretation of the pre-amendment MSP, "[t]he goals of finality would be frustrated, rather than furthered, by . . . wasteful and time-consuming procedures" and by "fruitless" reargurments on remand and reappeal. *Pennsylvania v. Ritchie*, 480 U.S. 39, 48 n.7 (1987). This Court should resolve the correct construction of the pre-amendment MSP because the reversal of the Eleventh Circuit's reasoning will establish the rule of law that will govern the outcome of thousands of claims.

CONCLUSION

For the reasons set forth above, the petition for a writ of certiorari should be granted.

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[28] By contrast, the Fifth and Second circuits will evaluate the retroactivity challenge in light of their construction of "self-insured plan." Indeed, the Fifth Circuit has likewise invalidated retroactive legislation as a violation of the Takings Clause, only increasing the potential depth of a split among the courts of appeals on the application and meaning of the MSP. *See, e.g., United States Fid. & Guar. Co. v. McKeithen*, 226 F.3d 412, 419-20 (5th Cir. 2000), *cert. denied*, 532 U.S. 922 (2001).

Respectfully submitted,

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APPENDIX

UNITED STATES COURT OF APPEALS
ELEVENTH CIRCUIT

United States of America,
Plaintiff-Appellant,
v.
Baxter International, Incorporated; Baxter Healthcare Corporation, et al.,
Defendants-Appellees,

Plaintiffs' Steering Committee,
Defendant-Intervenor-Appellee.

No. 01-16782

Sept. 15, 2003.

Appeal from the United States District Court for the Northern District of Alabama.

Before TJOFLAT, ANDERSON and CUDAHY,* Circuit Judges.

ANDERSON, Circuit Judge:

This case grows out of the 1995 settlement of a class-action products liability suit against manufacturers of silicone breast implants. The settlement resulted in the creation of a reimbursement mechanism by which several settling manufacturers agreed to cover certain health care expenses incurred by or on behalf of qualified members of

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* Honorable Richard D. Cudahy, United States Circuit Judge for the Seventh Circuit, sitting by designation.

the plaintiff class. The Government, as intervenor, sought to recover for medical bills it paid on behalf of Medicare beneficiaries who received treatment related to silicone breast implants. The district court dismissed the Government's Complaint in intervention for failure to state a claim. We conclude that the dismissal was in error. We therefore reverse and remand.

I. BACKGROUND

A. Historical Background

The underlying case is result of an order by the Judicial Panel on Multi-District Litigation, which consolidated all then-pending products liability claims against the manufacturers of silicone breast implants into a single action before the United States District Court for the Northern District of Alabama. The exact details of the underlying claims are not of significance to the disposition of the appeal before us. It is enough to observe that, in general, the plaintiffs allege that they suffered, or fear that they will contract, a variety of systemic illnesses traceable to silicone breast implants, necessitating in some instances that the implants be surgically removed at considerable expense.

The litigation resulted in a settlement valued at $4.2 billion that initially involved eight defendant manufacturers (the "*Lindsey* settlement"). On September 1, 1994, after conducting a fairness hearing, the district court approved the terms of the *Lindsey* settlement, with modifications. *See In re Silicone Gel Breast Implant Litig.*, No. CV 92-P-10000-S, MDL No. 926, Civ. A. No. CV94-P-11558-S, 1994 WL 578353 (N.D.Ala. Sept. 1, 1994) (approving modified settlement and redefining parameters of class membership). Subsequently, one of the larger defendants, Dow Corning, declared bankruptcy, and several other defendants (apparently dissatisfied with the court-imposed modifications) chose not to participate in the settlement, leaving the following companies as appellees now before us:

Baxter International, Inc.; Bristol-Myers Squibb Co., Minnesota Mining and Manufacturing Co. ("3M"); Union Carbide Corp.; and Union Carbide Chemical & Plastics Co.

After the modifications were publicized to class members, and after the settlement was restructured to take account of Dow Corning's bankruptcy filing, the district court gave final approval to the settlement by order of December 22, 1995. This became known as the "Revised Settlement Program," or RSP. The participating implant manufacturers are referred to collectively as "the RSP Defendants,"[1] the appellees before us.

The revised settlement class covered personal injury or death claims by members of a class consisting of: persons who received silicone breast implants before June 1, 1993; all children born to mothers with breast implants before April 1, 1994; and their spouses or other relatives. The Government,[2] as well as a number of private insurers, moved to intervene prior to approval of the settlement for purposes of asserting claims for reimbursement of medical claims paid on behalf of class members. The district court denied these motions as premature. Its order stated, in pertinent part: "The court will consider these issues at a later time, before any distributions ... are made, and

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[1] The settlement agreement purported to make the class claimants, rather than the RSP Defendants, liable for reimbursement claims by the Government or by other insurers. The district court did not, however, render its decision based on any agreement by the parties that the RSP Defendants were not liable. Wisely, none of the Defendants attempts to argue here that parties could override a statutory right of action afforded to the Government by a contractual arrangement to which the Government was not a party.

[2] When this case was initiated, the agency administering the Medicare program was known as the Health Care Financing Administration (HCFA), a subunit of the Department of Health and Human Services (HHS). Subsequently, the unit was renamed as the Centers for Medicare and Medicaid Services (CMS). For simplicity, we refer to the intervenor/appellant here as "HHS," "the Government" or "Medicare."

hopefully on the basis of motions that in some appropriate manner identify the persons on whose behalf subrogation claimants have paid medical expenses, rather than simply assert a general claim against the class."

In accordance with the settlement, the RSP Defendants created a Claims Office to review the documentation submitted by prospective class members and determine what level of benefits, if any, applicants were eligible to receive. Also as part of the claims process, the district court appointed an Escrow Agent, who is responsible for overseeing the investment and disbursement of the settlement proceeds. The position has been held since its inception by Edgar C. Gentile, III. The district court granted the Escrow Agent, as an agent of the court, "judicial immunity" for actions taken in his quasi-judicial capacity, unless he acts in the clear absence of jurisdiction.

The settlement resulted in the creation of two funds relevant to this case. The principal fund, called the RSP Settlement Fund (or sometimes MDL 926 Settlement Fund) is the account from which claims are paid. The second, the Common Benefit Fund, was created by a surcharge on the RSP Defendants for purposes of paying legal fees and expenses incurred for the "common benefit" of all claimants. Both funds are administered by the Escrow Agent.

The RSP Defendants made their first payment into the settlement fund in January of 1996, and at the direction of the district court, the Escrow Agent began issuing settlement payments to class members in mid-1996. According to the Government's Complaint, about 81,000 claimants had received some payment from the RSP as of April 1999. To date, more than 400,000 women have registered as potential claimants, and the RSP Defendants have paid more than $1 billion into the RSP Settlement Fund. More than 52,000 breast implant recipients opted out of the settlement class, according to the Complaint, and the

Defendants have made payments outside the RSP process to an unspecified number of them.

It is not clear from the record to what extent the RSP Defendants carried liability insurance coverage (other than "self insurance," about which more will be said shortly) for the events giving rise to the class members' claims, or to what extent these defendants have received compensation from such insurance for payments made into the two settlement funds. It is apparent that the implant companies had at least some liability coverage, because the settlement agreement expressly provides for the Defendants' insurers to have access to the otherwise confidential records of class claimants. We therefore take as established for purposes of this appeal that some third-party insurance coverage exists.

Beginning in 1995 and continuing through March of 2000, the Government entered into a series of "tolling agreements" with the RSP Defendants while negotiating over the Government's access to information about the settlement participants, for purposes of determining which class members may have received Government health benefits for which the Government was entitled to reimbursement. Under these tolling agreements, the Defendants agreed that they would not argue laches, statute of limitations or similar "timeliness" defenses if the Government was forced to file suit. In exchange, the Government agreed to forego filing suit during settlement negotiations. Negotiations between the Government and the RSP Defendants did not produce an agreement. Consequently, in March of 2000, the Government filed the complaint in intervention giving rise to this appeal.

B. The Medicare Secondary Payer (MSP) Statute

The Government's Complaint initially relied on two distinct but related statutes and their accompanying regulations: (1) the Medicare Secondary Payer ("MSP") statute, 42 U.S.C. § 1395y(b), and (2) the Medical Care

Recovery Act ("MCRA"), 42 U.S.C. § 2651. Although all of the Government's claims were dismissed, it is appealing only the dismissal of the MSP claim.[3]

The MSP is actually a collection of statutory provisions codified during the 1980s with the intention of reducing federal health care costs. *See Zinman v. Shalala*, 67 F.3d 841, 845 (9th Cir. 1995) ("The transformation of Medicare from the primary payer to the secondary payer with a right of reimbursement reflects the overarching statutory purpose of reducing Medicare costs."); *Provident Life & Accident Ins. Co. v. United States*, 740 F.Supp. 492, 498 (E.D.Tenn.1990) ("The intent of Congress in shifting the burden of primary coverage from Medicare to private insurance carriers was to place the burden where it could best be absorbed."). In a nutshell, the MSP declares that, under certain conditions, Medicare will be the secondary rather than primary payer for its insureds. Consequently, Medicare is empowered to recoup from the rightful primary payer (or from the recipient of such payment) if Medicare pays for a service that was, or should have been, covered by the primary insurer. Although the statute is structurally complex—a complexity that has produced considerable confusion among courts attempting to construe it—the MSP's function is straightforward. As we explained in *Cochran v. HCFA*, 291 F.3d 775, 777 (11th Cir.2002):

> [I]f payment for covered services has been or is reasonably expected to be made by someone else,

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[3] While the MSP statute is directed at recovery from "primary plans," the MCRA statute is directed at recovery from tortfeasors. It provides that, where the Government is obliged to pay for the medical care of a person who is injured "under circumstances creating tort liability upon some third person ... to pay damages therefor," the Government has the right to recover from the tortfeasor (or their insurers) the "reasonable value" of the care it provides. 42 U.S.C. § 2651(a); *see United States v. Haynes*, 445 F.2d 907, 908-09 (5th Cir.1971) (discussing history and purpose of MCRA statute).

> Medicare does not have to pay. In order to accommodate its beneficiaries, however, Medicare does make conditional payments for covered services, even when another source may be obligated to pay, if that other source is not expected to pay promptly.

Medicare originated as a series of amendments to the Social Security Act enacted in 1965, providing a source of payment for hospital care for those over 65. The program was, for the most part, the primary source of payment for its beneficiaries even when another source of coverage existed. However, the 1965 amendments also provided that coverage would be secondary to workers' compensation benefits, and that any payment to or on behalf of a Medicare beneficiary eligible for workers' compensation benefits would be contingent upon reimbursement. *See* S.Rep. No. 404 § 1862, 89th Cong., 1st Sess. (1965), *reprinted at* 1965 U.S.C.C.A.N. 1965, 2127-28 ("no payment may be made ... for any item or service for which payment has been made, or can reasonably be expected to be made, under a workman's compensation law or plan of the United States or a State. Any payment ... with respect to any [such] item or service must be conditioned on reimbursement being made to the appropriate trust fund for such payment if any when notice or other information is received that payment for such item or service has been made under such a law or plan."); *see also Parkview Hosp., Inc. v. Roese*, 750 N.E.2d 384, 388 (Ind.Ct.App.2001) (discussing early history and evolution of MSP statute). That language became the template for the modern MSP provision.

In pertinent part, the MSP statute in its current form provides:

(A) In general

Payment under this subchapter may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that—

> ... (ii) payment has been made or can reasonably be expected to be made promptly (as determined in accordance with regulations) under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no-fault insurance.
>
> In this subsection, the term "primary plan" means ... a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance, to the extent that clause (ii) applies.[4]
>
> (B) Repayment required
>
> (i) Primary plans
>
> Any payment under this subchapter with respect to any item or service to which subparagraph (A) applies shall be conditioned on reimbursement to the appropriate Trust Fund established by this subchapter when notice or other information

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[4] Part of the dispute in this case revolves around the meaning and scope of the statutory term "self-insured plan." Two HHS regulations are pertinent. Under 42 C.F.R. § 411.50(b), a "self-insured" plan "means a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier." Under 42 C.F.R. § 411.21, a "plan" is defined as "any arrangement, oral or written, by one or more entities, to provide health benefits or medical care or assume legal liability for injury or illness."

> is received that payment for such item or service has been or could be made under such paragraph.
>
> (ii) Action by United States
>
> In order to recover payment under this subchapter for such an item or service, the United States may bring an action against any entity which is required or responsible under this subsection to pay with respect to such item or service (or any portion thereof) under a primary plan (and may, in accordance with paragraph (3)(A) collect double damages against that entity), or against any other entity (including any physician or provider) that has received payment from that entity with respect to the item or service, and may join or intervene in any action related to the events that gave rise to the need for the item or service.
>
> (iii) Subrogation rights
>
> The United States shall be subrogated (to the extent of payment made under this subchapter for such an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

42 U.S.C. § 1395y(b)(2)(A)-(B). Subparagraph (b)(3)(A), which is referenced above, provides for a private right of action, with double damages available, if a primary plan "fails to provide for primary payment (or appropriate reimbursement) in accordance with" the preceding MSP regulations. *See* 42 U.S.C. § 1395y(b)(3)(A).

Pursuant to these provisions of the MSP statute, HHS has enacted regulations setting forth the means by which

the Government can bring an action to recoup payments from a primary coverage plan. These regulations read, in pertinent part:

> If a Medicare conditional payment is made, the following rules apply:
>
> (a) *Release of information.* The filing of a Medicare claim by or on behalf of the beneficiary constitutes an express authorization for any entity, including State Medicaid and workers' compensation agencies, and data depositories, that possess information pertinent to the Medicare claim to release that information to CMS. This information will be used only for Medicare claims processing and for coordination of benefit purposes.
>
> (b) *Right to initiate recovery.* CMS may initiate recovery as soon as it learns that payment has been made or could be made under workers' compensation, any liability or no-fault insurance, or an employer group health plan ...
>
> ... (e) *Recovery from third parties.* CMS has a direct right of action to recover from any entity responsible for making primary payment. This includes an employer, an insurance carrier, plan, or program, and a third party administrator ...
>
> ... (g) *Recovery from parties that receive third party payments.* CMS has a right of action to recover its payments from any entity, including a beneficiary, provider, supplier, physician, attorney, state agency, or private insurer that received a third party payment.

> (h) *Reimbursement to Medicare.* If the beneficiary or other party receives a third party payment, the beneficiary or other party must reimburse Medicare within 60 days.
>
> (i) *Special rules.* (1) In the case of liability insurance settlements and disputed claims under employer group health plans and no-fault insurance, the following rule applies: If Medicare is not reimbursed as required by paragraph (h) of this section, the third party payer must reimburse Medicare even though it has already reimbursed the beneficiary or other party.

42 C.F.R. § 411.24. Additionally, the regulations define "prompt" or "promptly," when used in connection with third-party payments, to mean "payment within 120 days after receipt of the claim." 42 C.F.R. § 411.21.

The MSP, in its present form, originated with enactment of the Omnibus Budget Reconciliation Act ("OBRA") of 1980, Pub. L. No. 96-499, § 953, 94 Stat. 2599 (1980). OBRA amended the Medicare Act to provide that Medicare payments "may not be made with respect to any item or service to the extent that payment has been made, or can reasonably be expected to be made (as determined in accordance with regulations) ... under an automobile or liability insurance policy ... or under no fault insurance."[5]

Since enacting the MSP statute, Congress has expanded its reach several times, making Medicare secondary to a greater array of primary coverage sources,

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[5] As the measure was originally proposed in the House, Medicare would have been secondary only to automobile insurance; a Senate amendment, adopted in conference, added no-fault and liability insurance. *See* House Conf. Rep. No. 96-14, 96th Cong., 2d Sess. 133, *reprinted in* 1980 U.S.C.C.A.N. 5903, 5924.

and creating a larger spectrum of beneficiaries who no longer may look to Medicare as their primary source of coverage.[6] More significantly for our purposes, Congress has repeatedly clarified and augmented the Government's powers to recoup conditional Medicare payments from primary sources.

The Deficit Reduction Act ("DERFA") of 1984 conferred on the Government a direct right of action to recover its payments from any entity "which would be responsible for payment" under a "law, policy, plan or insurance," and provided that the Government would be subrogated to the right of any individual or entity to receive payment. DERFA also modified the original wording of the secondary payment provision by adding the modifier "promptly," so that the pivotal phrase dictated that a Medicare payment "may not be made with respect to any item or service to the extent that payment has been made, or can reasonably be expected to be made promptly ... with respect to such item or service, under a workman's compensation plan or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or no-fault insurance[.]" H. Res. 4170, 98th Cong., 2d Sess., 98 Stat. 494 (1984) § 2344. In OBRA 1986, Congress added the private right of action for double damages codified at 42 U.S.C. § 1395y(b)(3)(A). It

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[6] In the Omnibus Budget Reconciliation Act of 1981, Congress augmented the MSP to provide that Medicare would be secondary to group health coverage for end-stage renal patients. H. Res. 3982, 97th Cong., 1st Sess., 95 Stat. 357 (1981) § 2146. In the Tax Equity and Fiscal Responsibility Act ("TERFA") of 1982, Congress made Medicare the secondary payer for "working aged" employees and their spouses between the ages of 65 and 69 belonging to large employer group health plans (covering twenty or more workers). H. Res. 4961, 97th Cong., 2d Sess., 96 Stat. 324 (1982) § 116. In the Omnibus Budget Reconciliation Act ("OBRA") of 1986, Congress made Medicare the secondary payer for disabled individuals enrolled in large employer group health plans. H. Res. 5300, 99th Cong., 2d Sess., 100 Stat. 1874 (1986) § 9319.

also added the cross-reference to that section in § 1395(b)(2)(B)(ii), which enables the Government to collect double damages "in accordance with" the new private right of action. H. Res. 5300, 99th Cong., 2d Sess., 100 Stat. 1874 (1986) § 9319.

II. THE DECISION BELOW

The Government's Complaint advanced nine counts: (1) a claim for reimbursement against the RSP Defendants as third-party payers under the MSP; (2) double damages against the RSP Defendants as third-party payers under the MSP; (3) single damages under the MSP against the RSP Defendants as entities that caused payments to be made, or received such payments, from product liability insurers; (4) a subrogation claim under the MSP against disbursements from the MDL Settlement Fund and/or the Common Benefit Fund; (5) a claim for declaratory relief that the RSP Defendants are liable under the MSP to reimburse Medicare for past payments to breast implant patients, and are obligated under 42 C.F.R. § 411.25 to provide Medicare with notice of all payments to Medicare beneficiaries; (6) a single damages claim under the MSP against the Escrow Agent as a person who received payment from the RSP Defendants and/or from product liability insurers to pay the claimants; (7) a claim for injunctive relief under the MSP to enjoin the Escrow Agent from making disbursements to Medicare patients pending resolution of Medicare's MSP claims and to compel disclosure of identifying information concerning all past or contemplated settlement payments to Medicare beneficiaries; (8) a claim for injunctive relief similar to Count VII under the MCRA, and (9) a demand under the MCRA for payment from the MDL Settlement Fund of the Government's reasonable costs for paying for care of Medicare patients for injuries alleged to be caused by a breast implant. Thus, Counts I through VII arose under

the MSP or its regulations, while counts VIII and IX arose under the MCRA.[7]

The district court (after first granting the Plaintiffs' Steering Committee the right to intervene) granted the motions to dismiss filed by the RSP Defendants, the Escrow Agent, and the Plaintiffs' Steering Committee, finding that the Government had failed to state a claim upon which relief could be granted.[8]

The court first evaluated whether the Government had a claim for reimbursement under 42 U.S.C. § 1395y(b), the MSP statute. The court found that—whether the Government was bringing a direct action in its own right under the statute or was acting as the subrogee to the patient's rights—an essential element to state a claim under the MSP was to identify both the services provided and the patient who received them. In addition to the need for the Defendants to know the identity of the patients and the amount in dispute, the court noted that the beneficiaries themselves are interested parties and have the right to challenge the reimbursement request and to petition the Government to waive its claim.

The court rejected the Government's argument that it was unable to plead the identity of the beneficiaries in question because of the settlement's confidentiality provisions. The court found that the Defendants were under no statutory duty to collect information about the identity of potential claimants, and that absent such a duty, it was irrelevant whether the settlement was structured with the purpose of evading disclosure. Because the Government had an alternative means of relief—like any other insurer, it could file a petition for reimbursement with

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[7] As noted above, the Government has now abandoned its MCRA claims.

[8] The opinion below was published as *In re Silicone Gel Breast Implants Products Liability Litig.*, 174 F.Supp.2d 1242 (N.D.Ala.2001).

the RSP Claims Office—the court found no need to relieve the Government from compliance with the MSP statute or the pleading standards of Fed.R.Civ.P. 8(a).

Next, the court considered whether the Government was entitled to reimbursement under 42 C.F.R. § 411.24(i), the "double payment" regulation adopted pursuant to the MSP. Under § 411.24(i), a "third party payer" may be required to reimburse Medicare if it paid a provider or a claimant when it knew, or should have known, that Medicare had made a conditional primary payment as provided by the MSP. The district court found this regulation inapplicable, because the relevant portion of the MSP statute applies only to insurers or "self-insured plans." The court rejected the Government's contention that the implant manufacturers could be viewed as "self-insured plans." The RSP Defendants were thus outside the coverage of the statute and not subject to the "double payment" regulation.

Further, the court found that the Government had no direct right of action against a third-party payer that had already made payment to its insured, because such a payer was no longer "required or responsible ... to pay" as provided by the MSP statute, § 1395y(b)(2)(B)(ii). The Government may proceed against such an insurer only in its role as subrogee, the court held. Relying on *Health Ins. Ass'n of America v. Shalala*, 23 F.3d 412 (D.C.Cir.1994) ("*HIAA*"), and on general principles of common law, the court held that, as a subrogee, the Government was required to "plead and prove [that] the third-party payer knew or should have known of Medicare's conditional payments at the time payment was made to the beneficiary." Because, in the district court's view, the Government failed to do so, its claims under the "double payment" provision were fatally flawed.

The court declined to adopt the Government's interpretation that the existence of the MSP statute itself

puts insurers on constructive notice that they must inquire into whether Medicare has paid a beneficiary before they pay a claim. Rather, citing *HIAA*, the court held that "knowledge" requires the Government to show that, at the time it paid the claim, the insurer had "direct information ... or information necessary to draw the conclusion" that Medicare had made a conditional payment to the particular recipient. It was insufficient, the court held, that the Government's prior intervention in the case *generally* alerted the Defendants that Medicare might have paid some claims.

The court rejected the Government's contention that the Defendants' knowledge was a factual matter to be proven at trial. The court observed that the Government's own complaint alleged that the RSP Defendants "did not ascertain" whether Medicare had made payments on behalf of any of the RSP claimants. With that assertion, the court felt that the Government had effectively pled itself out of court.

Next, the court addressed whether the Government could bring a claim in Count II against the RSP Defendants for double damages pursuant to 42 U.S.C. § 1395y(a)(3)(A) and 42 C.F.R. § 411.24(c)(2). Having held that the Defendants were not liable even for single damages, the district court summarily rejected the Government's claim for double damages.

Similarly, the district court summarily rejected the Government's claims for declaratory relief (Count V) and injunctive relief (Count VII). The court then considered whether any of the defendants could be liable under the MSP as entities that "received payment," as provided in 42 U.S.C. § 1395y(b)(2)(B)(ii). (Although the court acknowledged that the Government's claim under this section ran against both the RSP Defendants and the Escrow Agent, its discussion focused almost exclusively on

the role of the Escrow Agent.) First, the court—again relying on *HIAA*—held that a mere "pass-through" could not be said to have "received" payment under any ordinary understanding of that term, since "receipt" suggests a degree of autonomous control. Further, the court observed that the term "recover" in the statute suggested that the Government must proceed against an entity actually in possession of the money—either the ultimate payer or the ultimate payee—and not an entity that temporarily held the money and relinquished it. Additionally, the court observed that the Defendants did not fit either the statute's or HHS regulations' illustration of who qualifies as an entity that receives payment: the statute uses the illustration "any physician or provider," while 42 C.F.R. § 411.24(g) refers to "a beneficiary, provider, supplier, physician, attorney, State agency or private insurer that has received a third party payment." All of those entities, the court observed, are likely to be ultimate recipients of payment rather than mere conduits. Where an entity has merely remitted payment as a pass-through, the court held, that entity is reachable only through 42 C.F.R. § 411.24(i), which requires proof of knowledge of Medicare's prior payment that is lacking in this case.

III. DISCUSSION

We review a district court's grant of a motion to dismiss for failure to state a claim *de novo*. *ABATE of Georgia, Inc. v. Georgia*, 264 F.3d 1315, 1315 (11th Cir.2001). A motion to dismiss a complaint in intervention is reviewed under the same standard applicable to consideration of a motion to dismiss the original plaintiffs' complaint. *Southwest Ctr. for Biological Diversity v. Berg*, 268 F.3d 810, 819-20 (9th Cir.2001). In evaluating the sufficiency of a complaint under Rule 12(b)(6), courts must be mindful that the Federal Rules require only that the complaint contain "a short and plain statement of the claim showing that the pleader is entitled

to relief[.]" Fed.R.Civ.P. 8(a). In applying Rule 12(b)(6), "a complaint should not be dismissed for failure to state a claim unless it appears beyond a doubt that the [complainant] can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46, 78 S.Ct. 99, 102, 2 L.Ed.2d 80 (1957).

The district court granted the motion on two grounds: first, that the Government's Complaint was defective because it did not include the identity of the recipients of federal health care benefits and the nature of the expenditures, and second, that the MSP statute did not entitle the Government to proceed on its chosen theories against these defendants. Thus, we must consider both whether the Government has viable claims under the applicable law, and, if so, whether the Government's pleading was sufficient to invoke the MSP.

A. Sufficiency of Complaint

The district court held that, "at a minimum," a complaint under the MSP statute must identify the Medicare beneficiaries for whose care reimbursement is sought. Because the Complaint here failed to do so, the court held, the MSP counts were subject to dismissal.

Because the Federal Rules embody the concept of liberalized "notice pleading," a complaint need contain only a statement calculated to "give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Conley*, 355 U.S. at 47, 78 S.Ct. at 103; *see also Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC*, 148 F.3d 1080, 1086 (D.C.Cir.1998) ("[A] plaintiff need not allege all the facts necessary to prove its claim."). We have observed that the threshold of sufficiency to which a complaint is held at the motion-to-dismiss stage is "exceedingly low." *See In re Southeast Banking Corp.*, 69 F.3d 1539, 1551 (11th Cir. 1995 ("[F]or better or for worse, the Federal Rules of Civil Procedure do not permit district

courts to impose upon plaintiffs the burden to plead with the greatest specificity they can.").

Rule 24 requires merely that an intervenor's petition "shall state the grounds [for intervention] and shall be accompanied by a pleading setting forth the claim or defense for which intervention is sought." Fed.R.Civ.P. 24(e). "The determination of whether the proposed intervenor's complaint states a cause of action is controlled by the general rules on testing a pleading; the factual allegations of the complaint are assumed to be true ... and the pleading is construed liberally in support of the pleader." *Pin v. Texaco Inc.*, 793 F.2d 1448, 1450 (5th Cir.1986) (internal quotes and citation omitted); *accord County of Santa Fe v. Public Serv. Co. of N.M.*, 311 F.3d 1031, 1035 (10th Cir.2002).

The Supreme Court has said in the context of a standing determination that "[a]t the pleading stage, general factual allegations of injury resulting from the defendant's conduct may suffice, for on a motion to dismiss we presume that general allegations embrace those specific facts that are necessary to support the claim." *Nat'l Org. for Women, Inc. v. Scheidler*, 510 U.S. 249, 256, 114 S.Ct. 798, 803 127 L.Ed.2d 99 (1994) (*quoting Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561, 112 S.Ct. 2130, 2137, 119 L.Ed.2d 351 (1992)). In *Swierkiewicz v. Sorema, N.A.*, 534 U.S. 506, 511, 122 S. Ct. 992, 997, 152 L.Ed.2d 1 (2002), the Court held that in the employment discrimination context, a complaint is not subject to dismissal for failure to state a claim merely because it fails to "plead facts establishing a prima facie case" of discrimination. As the Court emphasized there:

> The liberal notice pleading of Rule 8(a) is the starting point of a simplified pleading system. ... Rule 8(a) establishes a pleading standard without regard to whether a claim will succeed on the merits. "Indeed, it may appear on the face of the

> pleadings that a recovery is very remote and unlikely but that is not the test."

Id. at 514, 122 S.Ct. at 999 (*quoting Scheuer v. Rhodes,* 416 U.S. 232, 236, 94 S.Ct. 1683, 40 L.Ed.2d 90 (1974)).

Courts typically allow the pleader an extra modicum of leeway where the information supporting the complainant's case is under the exclusive control of the defendant. *See Peters v. Amoco Oil Co.*, 57 F.Supp.2d 1268, 1284-85 (M.D.Ala.1999) (holding that complaint setting forth general allegations about nature of conspiracy was sufficient despite heightened pleading standard applicable to conspiracy claims under Fed.R.Civ.P. 9(b), where information about extent of alleged conspiracy was within defendants' exclusive control); *see also Quality Foods de Centro America, S.A. v. Latin American Agribusiness Dev. Corp.*, 711 F.2d 989, 995 (11th Cir.1983) (holding that liberalized consideration of complaint espoused in *Conley* "is particularly true in an antitrust suit where the proof and details of the alleged conspiracy are largely in the hands of the alleged co-conspirators.").

The situation presented here—an intervenor bringing a claim on the basis of injury to a large group of others, the identities of whom the intervenor claims cannot be determined without discovery—is not unlike that commonly presented in a class action, such as the one that underlies our case. In a class action, it is sufficient that a complaint generally give the defendant notice of the nature and scope of the plaintiffs' claims; it is not necessary that the class representatives plead evidence or otherwise meet any burden beyond the minimal Rule 8 standard. *See* 7B WRIGHT, MILLER & KANE, FEDERAL PRACTICE & PROCEDURE § 1798 (2d ed. 1986) at 417-18 ("All of the pleading provisions of the federal rules are applicable in class actions and operate in much the same fashion as they do in other litigation contexts. ... No greater particularity is

necessary in stating a claim for relief in a class action than in other contexts."); Alba Conte & Herbert B. Newberg, 6 NEWBERG ON CLASS ACTIONS § 18:46 (4th ed. 2003) ("It is not necessary ... that class members be specifically identified; the plaintiff need not name names. In addition, the complaint need not set forth the exact number of class members. It is sufficient to indicate the approximate size of the class and provide or describe facts making ultimate identification of class members possible when that identification becomes necessary."). Indeed, the Supreme Court's seminal statement of the standard for dismissal, *Conley*, involved a class action by African-American railroad clerks who alleged that their union had breached its duty of fair representation by discriminating against them.

In view of the foregoing, we find that the district court applied too exacting a standard when it found the Government's Complaint fatally deficient for failing to identify each member of the plaintiff class on whose behalf Medicare made a conditional payment.[9] The crucial information that the district court here found necessary to complete the Government's Complaint—"the Medicare beneficiaries who have received benefits from the defendants"—is outside the Government's control. At best,

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[9] In determining the required elements of a proper complaint, the district court placed principal reliance on *In re Dow Corning Corp.*, 244 B.R. 705 (Bankr. E.D. Mich. 1999), which involved Government claims under the MSP and MCRA seeking reimbursement from a manufacturer that opted out of this litigation. *See id.* at 713 (detailing necessary contents of Government's claims). Significantly, *Dow Corning* arose in the context of a Chapter 11 proceeding to validate the cramdown of a plan of reorganization, pursuant to 11 U.S.C. § 1129(b)(1), not in the context of a motion to dismiss. Consideration of a § 1129(b)(1) motion requires the court to review evidence and resolve issues of fact. Thus, the Government did not have the benefit of the deferential review afforded to allegations at the motion-to-dismiss stage. *Dow Corning*'s standard for what constitutes an adequately supported objection to the validation of a § 1129(b)(1) reorganization is of limited usefulness in determining what an ordinary civil complaint in intervention must contain.

the Government may be able to generate a list of all patients who received treatment for breast implant-related medical conditions during the period covered by the RSP settlement.[10] Such a list would be wildly over-inclusive, as it could include: patients whose implants were not manufactured by any of the RSP Defendants; patients who had their implants removed for reasons other than tortiously inflicted injury; patients who opted not to participate in the settlement; and patients participating in the class whose application for RSP benefits may (for whatever reason) not be approved by the Claims Office so that they will never receive payment. The Government could not in good faith purport to be bringing its Complaint on behalf of such a patently inaccurate list of beneficiaries. *See* Fed.R.Civ.P. 11(b) ("By presenting to the court ... a pleading, written motion, or other paper, an attorney or unrepresented party is certifying that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances ... the allegations and other factual contentions have evidentiary support"). While the Government might be able to arrive at a rough approximation, the RSP Defendants (either directly or through the Claims Office) have access to: (1) the names of the approximately 400,000 registered potential claimants, and (2) the approximately 81,000 people whose claims, to date, have been deemed worthy of payment. They are, consequently, in the far more advantageous position to compile an accurate list of Medicare patients for whom MSP payments have been made or requested.[11]

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10 Even this is a dubious assumption. Many women will doubtless have received Medicare-compensated treatment for generic symptoms not specifically identified on their providers' bills as related to breast implants, or perhaps not diagnosed as implant-related until later in the course of treatment.

11 The district court believed that the Government was required to plead the names of Medicare patients who have *actually received*

The pleading standards urged by the RSP Defendants are akin to the heightened requirements of Fed.R.Civ.P. 9, which apply to claims of fraud, mistake, duress and other "special matters." Where Rule 9 is implicated, plaintiffs must plead not only the general nature of their injuries but also the specifics of how and when they were injured. *See, e.g., Brooks v. Blue Cross & Blue Shield of Florida, Inc.*, 116 F.3d 1364, 1380-81 (11th Cir.1997) (under Rule 9(b), plaintiff alleging fraud must plead "(1) the precise statements, documents, or misrepresentations made; (2) the time, place, and person responsible for the statement; (3) the content and manner in which these statements misled the Plaintiffs; and (4) what the defendants gained by the alleged fraud"); *Coffey v. Foamex L.P.*, 2 F.3d 157, 161-62 (6th Cir. 1993) (Rule 9(b) requires plaintiff in fraud case "at a minimum, to allege the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud"). By implication, then, a complaint governed by the ordinary standard of Rule 8—and there is no dispute that applies here—need not allege the particulars of each instance of injury in order to survive a motion to dismiss.[12]

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payment from the Defendants. Because tens of thousands of pending claims remain to be evaluated by the RSP Claims Office, even if the Government were able to produce a perfectly accurate list in compliance with the district court's standards, such list would be obsolete essentially from the day of submission due to the ongoing claims adjudication process. We fail to see how the conduct of this litigation would be aided by forcing Medicare at this initial stage to produce what will necessarily be a grossly inaccurate and constantly changing claimant list.

[12] The Defendants argue that it would be inequitable to allow Medicare to proceed on the basis of an unspecific complaint when the Government failed to request access to the names of the RSP claimants—a request that the district court had indicated it might view favorably. Whether or not the Government conducted itself with optimal diligence is not conclusive. A complaint that is otherwise satisfactory under Rule 8—as is this one—does not become inadequate merely because the complainant

It is significant here that, out of a class of 400,000 potential claimants, it appears beyond dispute that at least some class members will have received conditional Medicare payments.[13] No one suggests to the contrary. Therefore, given the benefit of discovery, it appears not only possible but in fact inevitable that the Government will turn up a number of claims eligible for reimbursement. That the Government cannot now provide a name, date and dollar amount corresponding to any particular Medicare payment for which reimbursement is owed does not indicate beyond doubt that it has "no case," which is what a court must find to grant a motion to dismiss.[14]

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had access to more detailed information but failed to include it. (We note that the district court did not rely on the Government's failure to move for disclosure of the identity of the RSP claimants as a basis for dismissing the Complaint.)

[13] In a sworn declaration submitted to the district court in May 2000, the Government reported that 457 people (140 who participated in the RSP settlement and 317 who opted out) had identified themselves to HHS as having received payment from the breast implant litigation. This number hints at the immense litigation management problems that would ensue if the Government were forced to plead the individualized medical and payment histories of each of its beneficiaries.

[14] Our facts materially differ from those presented in *City of Birmingham v. American Tobacco Co.*, 10 F.Supp.2d 1257 (N.D.Ala.1998), on which the district court relied. In *City of Birmingham*, which involved a somewhat analogous claim for recovery of health care expenses under a state statute, the district court found that the plaintiffs were required to plead details about each patient and each expenditure for which reimbursement was sought. In that non-class action, however, there was considerable doubt as to whether the plaintiffs could identify even a single person for whose care they were entitled to reimbursement, and information as to the patients' identities and medical history was within the *plaintiffs'* exclusive control. It is also noteworthy that, even in *City of Birmingham*, the court did not dismiss the complaint outright, but rather, granted the plaintiffs leave to amend.

For similar reasons, we do not find the principal case cited by Defendants, *Health Care Serv. Corp. v. Brown & Williamson Tobacco Corp.*, 208 F.3d 579 (7th Cir.2000), to be on point. In *Brown & Williamson*, the Seventh Circuit upheld the dismissal of a subrogatory claim by various Blue Cross/Blue Shield associations suing tobacco

Finally, we note that requiring the Government to plead with the specificity Defendants seek would run counter to the intent of the MSP statute. In carrying out its principal purpose of shifting the burden of paying for health care from Medicare to private insurers, the MSP creates as a practical matter a need for insurers to determine, before paying a disputed liability claim (involving among its alleged damages medical expenses likely to have been paid by Medicare), whether the Government has made a conditional payment, upon peril of being forced to pay the same claim twice. As the second payer, such insurer is in a position to determine which claim has been, or is at risk of being, paid twice, while Medicare, as the first payer, is not. Because the statute is built on the recognition that Medicare frequently will not know which of its payments has been subsequently duplicated by an insurer, it would—in this unique setting of a class action involving thousands of claimants—defeat the purpose of the statute to require that the Government identify each patient, procedure, and payment amount at the pleading stage without benefit of discovery.

We readily conclude that the district court erred in dismissing the complaint for failure to identify the beneficiaries for whose care reimbursement is sought.

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companies to recover for smoking-related health care expenses for their insureds. Although the court did find the complaint lacking because it failed to plead the identity of the parties insured, its principal weakness was a failure to show either a right to recovery or a basis for federal jurisdiction, both of which are supplied in our case by the MSP statute. Moreover, as with *City of Birmingham*, *Brown & Williamson* did not arise out of an underlying class action, which (in our case) itself serves to give the defendants notice of the universe of patients for whose expenses reimbursement may be sought.

B. Scope of MSP Statute

1. Were Medicare's payments conditioned on reimbursement?

The RSP Defendants argue here that the Government's right to recoup its payments never arose, because under the terms of the MSP statute, Medicare's payments were not "conditional" at all. The disputed statutory provisions, 42 U.S.C. §§ 1395y(b)(2)(A) and (b)(2)(B), provide:

> (A) In general
>
> Payment under this subchapter may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that—
>
> (i) payment has been made, or can reasonably expected to be made, with respect to the item or service as required under [regulations governing group health plans], or
>
> (ii) payment has been made or can reasonably be expected to be made promptly (as determined in accordance with regulations) under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no-fault insurance. ...
>
> In this subsection, the term "primary plan" means a group health plan or large group health plan, to the extent that clause (i) applies, and a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance, to the extent that clause (ii) applies.
>
> (B) Repayment required
>
> (i) Primary plans

> Any payment under this subchapter with respect to any item or service to which subparagraph (A) applies shall be conditioned on reimbursement to the appropriate Trust Fund established by this subchapter when notice or other information is received that payment for such item or service has been or could be made under such paragraph.

Defendants argue that subparagraph (A) operates as a limitation on the right of reimbursement in subparagraph (B), so that a Medicare payment is conditioned on reimbursement only if "payment has been made or can reasonably be expected to be made promptly" by another insurer. In other words, Defendants argue that Medicare is entitled to reimbursement only if Medicare pays after payment from a primary insurance source either has already been made or is expected promptly. Otherwise, in Defendants' view, Medicare's payment is unconditional and may not be recouped.

Grammatically, Defendants' interpretation is a possible reading of the statute. However, we think the much more plausible interpretation of the statute is that Medicare would endeavor not to pay where a "primary plan" has paid or is expected to pay promptly, but any payment that Medicare does make is secondary and is subject to reimbursement from sources of primary coverage under the statute. This more plausible interpretation is also a grammatically correct construction of the language of the statute. The crucial phrase in § 13957(b)(2)(B)(i)—"to which subparagraph (A) applies"—plausibly modifies "any item or service," meaning any item or service covered by a primary plan as defined in the last paragraph of § 1395y(b)(2)(A). The court in *Brown v. Thompson*, 252 F.Supp.2d 312, 317 (E.D.Va.2003) recently rejected Defendants' interpretation,

and adopted the interpretation we adopt today. The *Brown* court held:

> [T]he reference in subparagraph B to "item or service to which subparagraph A applies" must refer only to that portion of subparagraph A that defines a primary plan. In other words, the reference to subparagraph A in subparagraph B serves simply to define the universe of reimbursable payments to consist of those where primary coverage exists. ... Properly construed, therefore, subparagraph B requires reimbursement for a payment, as here, that "has been made" from a "primary plan" as defined in subparagraph A.

It is clear that an item or service paid by a primary plan defined in the last paragraph of subparagraph (A) is, in the language of subparagraph (B), an "item or service to which subparagraph (A) applies." In other words, subparagraph (A) applies by defining the universe of reimbursable payments.

Our interpretation is further supported by a close examination of the language of subparagraphs (A) and (B). Subparagraph (B) refers to payments "with respect to any item or service to which subparagraph (A) applies." This would include any payments contemplated by subparagraph (A). Turning to subparagraph (A) to ascertain what payments it contemplates, we see that it contemplates that Medicare should *not* pay if payment has been made or is reasonably expected from a group health plan (subparagraph (A)(i)), and that Medicare should *not* pay if payment has been made or can reasonably be expected to be made promptly under plans including liability insurance or self-insured plans (subparagraph (A)(ii)). By contrast subparagraph (A) clearly contemplates Medicare will pay when it does not reasonably expect prompt payment by such primary obligors—precisely the payments which

Defendants argue are not reimbursable. We believe that the much more plausible interpretation of the statutory language indicates that these payments are reimbursable. These are payments "with respect to any item or service to which subparagraph (A) applies" because subparagraph (A) defines their universe and contemplates Medicare paying them.

Although only our more plausible interpretation comports with the purpose of the statute, *see infra*, the two grammatically correct potential interpretations mean that the statute might be considered ambiguous. Where such ambiguity exists, the reasonable interpretation of the agency charged with implementing the statute is entitled to judicial deference, under the principles enumerated by the Supreme Court in *Chevron USA, Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984).

The first step in the two-step *Chevron* review is to determine whether Congress has "directly and unambiguously spoken to the precise question at issue." *Georgia Dept. of Med. Assistance v. Shalala*, 8 F.3d 1565, 1567 (11th Cir.1993) ("*Georgia DMA*") (*quoting Chevron*, 467 U.S. at 842-43, 104 S.Ct. at 2781-82). If so, the court's inquiry is at an end, for it must honor Congress' clearly expressed intent. Determining whether Congress has unmistakably addressed the issue requires looking at "the particular statutory language at issue, as well as the language and design of the statute as a whole." *Georgia DMA*, 8 F.3d at 1567 (citing *Sullivan v. Everhart*, 494 U.S. 83, 89, 110 S.Ct. 960, 964, 108 L.Ed.2d 72 (1990)).

If Congress has not directly addressed the issue, or the statutory provision is ambiguous, we come to the second stage of *Chevron*: whether the agency's construction of the statute is reasonable and consistent with congressional intent. If so, we must accede to it. *See Dawson v. Scott*, 50

F.3d 884, 887 (11th Cir.1995) ("Agency interpretation is reasonable and controlling unless it is 'arbitrary, capricious, or manifestly contrary to the statute.'") (*quoting Chevron*, 467 U.S. at 844, 104 S.Ct. at 2782); *Bigby v. INS*, 21 F.3d 1059, 1063 (11th Cir.1994) ("[W]e defer to an agency's reasonable interpretation of a statute it is charged with administering."). The consistency of an agency's interpretation over time is a factor in determining the level of deference due. *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417, 113 S.Ct. 2151, 2161, 124 L.Ed.2d 368 (1993); *see also Teamsters v. Daniel*, 439 U.S. 551, 566 n. 20, 99 S.Ct. 790, 800 n. 20, 58 L.Ed.2d 808 (1979) ("It is commonplace in our jurisprudence that an administrative agency's consistent, longstanding interpretation of the statute under which it operates is entitled to considerable weight.").

Here, we find that HHS—which was expressly delegated by Congress to formulate rules implementing the MSP statute—has consistently taken the position that Medicare payments are conditional and subject to recoupment regardless of whether another insurer can be expected to render a prompt primary payment. We start with the agency's notion of what it means for a Medicare payment to be "secondary." HHS regulations state that "'[s]econdary,' when used to characterize Medicare benefits, means that those benefits are payable only to the extent that payment has not been made and cannot reasonably be expected to be made under other insurance that is primary to Medicare." 42 C.F.R. § 411.21. In other words, the regulation rejects Defendants' interpretation, and embraces our interpretation—that conditional medical payments are made to beneficiaries whose primary coverage has not yet paid and is not expected to pay promptly.

In updating its regulations to account for congressional revisions in 1984 through 1987, the agency stated its

understanding that "Medicare makes conditional primary payment only if the other insurer will not pay promptly." Medicare as Secondary Payer and Medicare Recovery Against Third Parties, 53 Fed. Reg. 22335, 22336 (proposed June 15, 1988). Similarly, in characterizing Congress' 1987 revisions to the secondary payment provisions regarding coverage for end-stage renal patients, HHS stated: "Medicare may not make conditional primary payments on behalf of an ESRD beneficiary who is covered by an employer group health plan if the plan 'can reasonably be expected' to pay." Medicare as Secondary Payer and Medicare Recovery Against Third Parties, 54 Fed. Reg. 41716, 41717 (Oct. 11, 1989); *see also* Medicare Program, Services Covered Under Automobile Medical, No-Fault, or Liability Insurance; Services Furnished to ESRD Beneficiaries Who Are Covered Under Employer Group Health Insurance, 48 Fed. Reg. 14802, 14807 (April 5, 1983) ("Congress clearly intended that Medicare not pay first when there is a reasonable expectation that the employer plan will pay as promptly as Medicare. ... Medicare will be primary payer for items and services not covered by the employer plan and will make conditional primary payments if the intermediary or carrier determines that the employer plan will not pay promptly."). These and other authoritative HHS interpretations evidence that the agency has always understood that it will endeavor not to make payments where a payment has already been made by, or can reasonably be expected to be made by, a primary insurer, but that payment may be made conditionally under § 1395y(b)(2)(B) when Medicare does not reasonably expect prompt primary coverage payment.

We find the agency's interpretation to be in accord with the structure, history and purpose of the MSP statute, all of which plainly indicate that Congress wanted Medicare's payments to be secondary and subject to recoupment in *all*

situations where one of the statutorily enumerated sources of primary coverage could pay instead. It is readily apparent that the interpretation evidenced in the HHS regulations, which we also adopt, correctly implements the statutory purpose. The RSP Defendants do not deny that the clear statutory purpose of the Medicare Secondary Payer statute was to make Medicare's obligation secondary to that of designated primary obligors, with the intention of reducing federal health care costs. This statutory purpose is universally accepted. It is also clear that HHS' interpretation would fulfill the congressional purpose, while Defendants' interpretation would frustrate that purpose.[15]

Next we turn from the foregoing general purpose of the statute to the specific language which Defendants argue supports their interpretation: "Any payment under this subchapter with respect to any item or service to which subparagraph (A) applies shall be conditioned on reimbursement. ..." § 1395y(b)(2)(B)(i). Defendants argue that subparagraph (A) refers to situations where the primary obligor has already paid or can be expected to pay promptly; thus, Defendants argue that Medicare payments are conditional only in such situations. However, subparagraph (A) makes it clear that those are the very situations in which Medicare should endeavor *not* to pay. Thus, Defendants' interpretation would require us to indulge the illogical premise that Congress intended for Medicare to pay claims that it knew for a fact had already

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[15] If Medicare's payments were conditional only if Medicare paid when the primary obligor had already paid or was expected to pay promptly, as Defendants would have us hold, then the vast majority of Medicare payments for services also covered by primary obligors would not be conditional. This is so because the only payments Defendants want to label as conditional are the very payments which § 1395y(b)(2)(A) provides Medicare should not make at all. Thus, Congress' cost-saving measures would have borne little or no fruit.

been paid, or were about to be paid, by the primary obligor—the very claims which the statute clearly contemplates that Medicare would endeavor not to pay.

Thus, both the general statutory purpose, and the purpose evident in the very language upon which Defendants rely, is manifestly inconsistent with Defendants' interpretation. By contrast, our interpretation, and that adopted by the regulations, fully implements the general congressional purpose, and is consistent with both the purpose and the precise language of §§ 1395y(b)(2)(A) and (B). In our view, Congress intended that Medicare would *always* be secondary to the sources of primary coverage enumerated in the statute.

Our interpretation not only fulfills the statutory purpose, but is consistent with the congressional intent as evidenced in the legislative history. Congress quite clearly expressed its understanding of how the secondary payment mechanism was designed to work in 1984, when enacting amendments that clarified the Government's direct and subrogatory rights against third-party payors:

> The bill establishes the statutory right of medicare [sic] to recover directly from a liable third party, if the beneficiary himself does not do so, and to pay a beneficiary, or on the beneficiary's behalf *pending recovery where such third party is not expected to pay promptly*.

H.R.Rep. No. 98-432, at 1803 (1984), *reprinted in* 1984 U.S.C.C.A.N. 697, 1417 (emphasis added). Unmistakably, Congress intended that contingent payments made because the primary payer was not expected to pay promptly would be subject to recovery.

The legislative history of the MSP indicates that it originated as a device to recoup payments from automobile insurance coverage. *See Mason v. American Tobacco Co.*, 212 F.Supp.2d 88, 93 (E.D.N.Y.2002) (quoting original

House bill, which referred only to "automobile insurance"). It is not at all uncommon for automobile insurance claims to be litigated and thus to take more than 120 days to be resolved. *See, e.g., Waters v. Farmers Texas County Mut. Ins. Co.*, 9 F.3d 397 (5th Cir.1993) (denying summary judgment on MSP claim arising out of automobile accident three years earlier and remanding case for trial). The same is true of workers' compensation claims, which have been included within the scope of the MSP since its inception. Indeed, Medicare regulations specifically contemplate recovery where the third-party payment is the result of a judgment or a litigation settlement, which as a practical matter will almost always take more than 120 days. *See* 42 C.F.R. § 411.37 (providing that Medicare will deduct from its recovery a pro rata share of attorney fees and other "procurement expenses" incurred to secure a judgment or settlement). Congress fully contemplated such delays when it provided for Medicare to pay contingently. *See* H.R.Rep. No. 1167, 96th Cong., 2d Sess., at 389 (1980) ("Medicare will ordinarily pay for the beneficiary's care in the usual manner and then seek reimbursement from the private insurance carrier after, and to the extent that, such carrier's liability under the private policy for the services has been determined."). If the Defendants' interpretation were correct, it could well preclude recovery from automobile liability or workers' compensation insurance—the very sources for which the MSP was designed—since those sources routinely pay claims more than 120 days after the provision of medical treatment.

The historical evolution of these statutory provisions also supports the interpretation adopted by the agency. When Congress expanded the secondary payer provision in the Omnibus Budget Reconciliation Act of 1981 so that it would include those enrolled in federal employee health

plans and end-stage renal patients covered by group health plans, the provision read as follows:

> (2)(A) In the case of an individual who is entitled to benefits under [Medicare] part A or is eligible to enroll under part B ... payment under this title may not be made, except as provided in subparagraph (B), with respect to any item or service furnished during the period described in subparagraph (C) to the extent that payment with respect to expenses for such item or service (i) has been made under any group health plan ... or (ii) the Secretary determines will be made under such a plan as promptly as would otherwise be the case if payment were made by the Secretary under this title.
>
> (B) Any payment under this title *with respect to any item or service to an individual described in subparagraph (A)* during the period described in subparagraph (C) shall be conditioned on reimbursement to the appropriate Trust Fund established by this title when notice or other information is received that payment for such item or service has been made under a plan described in subparagraph (A).

See H. Res. 3982, 97th Cong., 1st Sess., 95 Stat. 357 (1981) (emphasis added). Thus, in the 1981 version, it is clear that subparagraph (B) incorporates subparagraph (A) only to indicate that the two subparagraphs apply to the same set of *individuals*—those entitled to benefits under Medicare Part A or eligible to enroll in Medicare Part B—not to the same set of *payments*.

In the Tax Equity and Fiscal Responsibility Act of 1982 (TERFA), Congress revised the MSP provision so as to make Medicare the secondary payer for "working aged" recipients under age 70 and their spouses enrolled in

employer group health plans. TERFA added the following conditional payment provision to 42 U.S.C. § 1395y:

> (3)(A)(i) Payment under this title may not be made, except as provided in clause (ii), with respect to any item or service furnished ... to an individual who is over 64 but under 70 years of age ... who is employed at the time such item or service is furnished to the extent that payment with respect to expenses for such item or service has been made, or can reasonably be expected to be made, under a group health plan ...
>
> (ii) Any payment under this title with respect to *any* item or service ... shall be conditioned on reimbursement to the appropriate Trust Fund ... when notice or other information is received that payment for such item or service has been made under a group health plan.

H. Res. 4961, 97th Cong., 2nd Sess., 96 Stat. 324 (1982) (emphasis added). The conditional payment provision, in this iteration, patently applied to *any* item or service for which a group health plan might pay. It in no way limited the Government's right of recovery to those items or services for which a third-party payment was made or reasonably anticipated before Medicare made its payment.

Congress again amended the MSP in 1986 with the purpose, *inter alia*, of prohibiting employer group health plans from offering lesser benefits to senior citizens based on their Medicare eligibility. At that point, the "secondary payer" provision read:

> (4)(A)(i) A large group health plan may not take into account that an active individual is eligible for or receives benefits under this title ...
>
> (ii) Payment may not be made under this title, except as provided in clause (iii), with respect to any item or service to the extent that payment has

> been made, or can reasonably be expected to be made, with respect to the item or service as required under clause (i).
>
> (iii) Any payment under this title *with respect to any item or service to which clause (i) applies* shall be conditioned on reimbursement to the appropriate Trust Fund established by this title.

See H. Res. 5300, 99th Cong., 2nd Sess., 100 Stat. 1974 (1986). In this incarnation, Medicare's right of reimbursement in subparagraph (A)(iii) (what is now subparagraph (B)) refers back to and incorporates subparagraph (A)(i), which concerns the duty of large group health plans to render primary payment. Again, this version makes clear that the reference to subparagraph (A) in Medicare's right of reimbursement merely characterizes the broad *category of coverage* to which Medicare will be secondary. It cannot possibly be read as limiting Medicare's right of recovery to payments made after a group health plan has already paid or is expected to pay.

The current wording of the MSP was adopted as part of the Omnibus Budget Reconciliation Act of 1989, H. Res. 3299, 101st Cong., 1st Sess., 103 Stat. 2186 (1989). There is no indication in the legislative history that, between 1986 and 1989, Congress changed its mind and decided that Medicare should cease being the secondary payer for a substantial subset of claims.[16] Although the 1989

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[16] To the extent that there is any record of legislative intent at all, it indicates that Congress was dissatisfied that Medicare was not recouping as much from primary payers as it could; there is not the slightest indication of congressional sentiment that Medicare was recovering too much. *See* 136 Cong. Rec. S13419-01 (daily ed. Sept. 19, 1990) (statement of Sen. Roth) ("Unfortunately, performance under the MSP Program has not measured up. Failure to follow the MSP law is costing the taxpayer billions of dollars. ... Studies by the General Accounting Office and the inspector general of the Department of Health and Human Services have repeatedly identified the MSP program as gushing with leaks of Federal

amendments obscured the clarity of the prior versions of the conditional payment provision, we cannot glean from this obscurity an unambiguous legislative purpose to narrow the MSP in the way that Defendants urge.

Our view is further sharpened by Congress' addition of the modifier "promptly" in 1984. Defendants have offered no logical explanation, and we can discern none, for why Congress would have intended to divest Medicare of the right to pursue recovery if payment from another insurer was probable, yet—because of a coverage dispute—unlikely to occur within the 120-day window of "promptness."[17] Rather, it is apparent that the concern for "promptness" is motivated by a desire to prevent either the health care provider or the patient from going without compensation for a prolonged period while an insurance dispute is being

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tax dollars."); 135 Cong. Rec. S11848-01 (daily ed. Sept. 26, 1989) (statement of Sen. Durenberger) (discussing, in context of FY 1990 appropriations bill for health agencies, inadequacy of expenditures by Medicare intermediaries on MSP recoupment activity). In the 1989 OBRA legislation containing the confusing passage which is the subject of this dispute, Congress simultaneously enacted measures augmenting Medicare's ability to identify the existence of primary coverage, by giving HHS access to data from the IRS and the Social Security Administration. In so doing, Congress indicated in its statement of intent that "[u]nder current law, HHS is unable to identify all Medicare secondary payer situations, principally because HHS is unable to identify cases in which Medicare beneficiaries have primary coverage through a spouse's plan." H.R.Rep. 101-247, at 1021, *reprinted in* 1989 U.S.C.C.A.N. 1906, 2492 (1989). Nothing in the statement of intent indicates a desire to restrict Medicare's ability to recover conditional payments, or a realization that the 1989 amendments would be so construed.

[17] Suppose, for instance, that a Medicare patient was injured as the result of a multi-party automobile accident in which each motorist carried private insurance, yet each insurer refused to pay until liability could be sorted out among the participants. Even though it was certain that some insurer would ultimately pay—the only question being which—Defendants' interpretation would deprive Medicare of the ability to lay claim to the insurance proceeds if Medicare made a conditional payment on the basis that private payment was not "promptly" forthcoming.

resolved. Indeed, that is exactly how Congress—in enacting an earlier iteration of the MSP—explained its insertion of the term "promptly" in determining when Medicare may pay conditionally. *See* H.R.Rep. No. 208, 97th Cong., 1st Sess. 955, 956 (1981), *reprinted in* 1981 U.S.C.C.A.N. 396, 1318 ("The payment arrangements contemplated by the conferees are intended to minimize patient anxiety about the source of payment and to avoid delays in reimbursement for expenses incurred in connection with the use of [medical] equipment, supplies or services."); *see also Nat'l Ass'n of Patients on Hemodialysis & Transplantation, Inc. v. Heckler*, 588 F.Supp. 1108, 1128 (D.D.C.1984) (explaining that Congress' decision to allow Medicare to pay conditionally when group health plan was not expected to render prompt payment "was a response to the conferees' concern about patient anxiety regarding the source of promptness of payment and delays in reimbursement"); *Brown*, 252 F.Supp.2d at 319 ("The sole purpose of the phrase 'reasonably expected to be made promptly' in subparagraph A is to ensure that needed Medicare payments are not delayed to the detriment of a Medicare beneficiary"). It is for that reason that, even where Medicare reasonably anticipates that another insurer will pay eventually, it may pay conditionally if the dispute over primary coverage is likely to last more than 120 days.

Although the agency interpretation finds overwhelming support in the congressional purpose and legislative history, the case law has been less uniform. Several courts have accepted Defendants' view that Medicare's payment is conditional and subject to recoupment only in the circumstances described in one portion of subparagraph (A): the rightful primary insurer has paid, or is expected to do so promptly. *See In re Dow Corning Corp.*, 250 B.R. 298, 348 (Bankr.E.D.Mich.2000); *In re Diet Drugs*, No. MDL 1203, Civ.A. 99-20593, 2001 WL 283163 at * 11 n. 20 (E.D.Pa.

March 21, 2001); *In re Orthopedic Bone Screw Prod. Liability Litig.*, 202 F.R.D. 154, 167-68 (E.D.Pa.2001).[18]

However, in *Cochran v. HCFA*, 291 F.3d 775 (11th Cir.2002), our dicta read the statute in accordance with the Government's more expansive view. *See id.* at 777 ("In order to accommodate its beneficiaries ... Medicare does make conditional payments for covered services, even when another source may be obligated to pay, if that other source is not expected to pay promptly."). That is the way most other courts have interpreted it. *See Rybicki v. Hartley*, 792 F.2d 260, 262 (1st Cir.1986) (Breyer, J.) ("Taken literally, [the MSP] simply says (in respect to a Medicare subscriber with a private source of insurance), 'if we can be reasonably certain that the insurance company will pay, Medicare won't pay; if we cannot be certain, Medicare will pay, but then, if the company pays you, you must reimburse Medicare.'") (parenthetical in original); *accord Evanston Hosp. v. Hauck*,

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[18] In *Thompson v. Goetzmann*, 315 F.3d 457 (5th Cir. 2002), the Fifth Circuit originally accepted the premise that the Government's right of recovery under the MSP was limited to situations in which another primary coverage source had paid or was expected to pay promptly. *See id.* at 468. Upon the Government's petition for rehearing *en banc*, however, the panel withdrew its opinion and issued an amended opinion which, while reaching the same ultimate result, no longer relied upon the limited construction of subparagraph (A) that Defendants advance here. *See Thompson v. Goetzmann*, 337 F.3d 489 (5th Cir.2003) (amending initial *Goetzmann* decision). In a preface to the amended opinion, the court stated that, while it remained convinced that the statute's wording supported its original conclusion that the Government may not collect from a primary plan unless such plan is expected to pay promptly, it recognized that its interpretation risked producing an "absurd result ... [that] precludes the right to reimbursement from any disputed or potentially disputed funds," since a disputed fund could never be expected to pay promptly. *See id.* at 492. We agree with the most recent Fifth Circuit opinion that the interpretation urged by Defendants, and accepted by the courts cited above, produces an absurd result. Moreover, we point out in the text above that this result is not indicated by the plain language of the statute. Rather, our construction is a much more plausible construction of the plain language of the statute.

1 F.3d 540, 544 (7th Cir.1993) (citing *Rybicki*, "[t]he Medicare law ... forbids payment where a third party can reasonably be expected to make prompt payment," and conversely, Medicare is allowed to pay conditionally where contested tort litigation cannot be expected to yield prompt payment); *Smith v. Farmers Ins. Exchange*, 9 P.3d 335, 338-39 (Colo.2000) (en banc); *Brown*, 252 F.Supp.2d at 317; *Oregon Ass'n of Hosps. v. Bowen*, 708 F.Supp. 1135, 1140-41 (D.Or.1989); *Vogt v. Wausau Hosps., Inc.*, No. 93- 2707, 516 N.W.2d 791, 1994 WL 246552 at * 2 (Wis.App.1994); *see also* Thomas J. Nyzio, *Medicare Recovery in Liability Cases*, S.C. LAWYER, May/June 1996, at 20, 21-22 ("Under the statute, payment may not be made with respect to any item or service to the extent that payment has been made, or prompt payment ... can reasonably be expected to be made, under a liability or no fault insurance policy or plan. However, payments can be made in the event that a provider will not receive prompt payment from a third party payer or from the proceeds of a liability settlement or judgment. These payments, however, are conditioned on reimbursement to Medicare in the event that payment for the same services is received from a liability or no fault insurer.") (citations omitted); Susan G. Haines & Tomas D. Begley, Jr., *Workers' Compensation Medicare Set-Aside Trusts*, ABA Brief/Practice Tips (Fall 2001) ("Medicare may make a conditional payment for services if Medicare does not reasonably expect the third-party insurer to make its primary payment promptly.").

In summary, we conclude that the agency's interpretation is eminently reasonable. Indeed, the agency's interpretation follows the most plausible interpretation of the statutory language, and is the only construction of the language which is consistent with the clear statutory purpose. Both the legislative history and the uninterrupted history of revisions to the MSP statute support this

interpretation. We have no doubt that payments made by Medicare on behalf of breast-implant patients were conditioned upon reimbursement if the patients later recovered from one of the primary sources enumerated in 42 U.S.C. § 1395y(b)(2)(A).

2. Do the RSP Defendants qualify as "self-insured," so that their payments to the class members were made "under a primary plan" and thus subject to a recoupment action under the MSP statute?

The Government contends that the RSP Defendants are liable under the MSP statute on the basis that they operated under a "self-insured plan."[19] The parties dispute whether the Government's Complaint alleged the existence of a self-insured plan with sufficient detail. In its opinion, 174 F.Supp.2d at 1254-55, the district court expressed its relevant holdings in several articulations, which we number for ready reference:

(1) that a "'self-insured plan' connotes some type of formal arrangement ..."

(2) "... by which funds are set aside and accessed to cover future liabilities;"

(3) "[P]ayments [by a tortfeasor], without more, [do not] constitute a 'plan' of self-insurance;"

(4) "The mere absence of insurance purchased from a carrier does not necessarily constitute a 'plan' of self-insurance" (quoting 54 Fed. Reg. 41727 (Oct. 11, 1989)); and

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[19] The Government concedes that the RSP settlement mechanism, which antedated the Government's Medicare payments, is not a "self-insured plan" as that term is understood in 42 U.S.C. § 1395y(b)(2)(A)(iii). Rather, the Government's theory is that the individual companies were each operating under a plan of self-insurance in which they arranged to purchase third-party liability coverage and self-insure up to the amount of their policies' deductibles.

(5) "Payments of deductibles ... do not constitute a 'plan' of self-insurance."

We agree with the district court as to the first, third and fourth holdings, but not as to the second and fifth.

There is remarkably little legal authority (none binding in our Circuit) categorically defining what it means to operate a "self-insurance plan." Black's Law Dictionary defines "self-insurance" as: "The practice of setting aside a fund to meet losses instead of insuring against such through insurance. A common practice of businesses is to self-insure up to a certain amount, and then to cover any excess with insurance." BLACK'S LAW DICTIONARY 1220 (5th ed. 1979). The first sentence of the dictionary definition suggests that an advance set-aside of funds would usually be a part of a self-insurance plan.[20] *See Jackson v. Donahue*, 193 W.Va. 587, 457 S.E.2d 524, 528 (1995) ("The phrase 'self-insurance' means, generally, the assumption of one's own risk and, typically, involves the setting aside of a special fund to meet losses and pay valid claims[.]"); COUCH ON INS.3d § 10:1 (stating that, while "[t]he term 'self-insurance' has no precise legal meaning," it generally implies "the same sort of underwriting procedures that insurance companies employ," such as estimating likely losses and setting aside reserves).

Other authorities, however, suggest a more elastic definition. *See In re Amatex Corp.*, 107 B.R. 856, 872

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[20] However, the second sentence is not inconsistent with the commonly understood practice of self-insuring up to a certain amount, and then covering any excess with insurance, often with no set-aside of funds.

A more recent edition of Black's defines "self-insurance" as simply: "A plan under which a business sets aside money to cover any loss." The same edition defines "self-insured retention" as: "The amount of an otherwise-covered loss that is not covered by an insurance policy and that [usually] must be paid before the insurer will pay benefits." BLACK'S LAW DICTIONARY 807, 1365 (7th ed. 1999). This definition, like its predecessor, suggests that self-insurance can be understood both as the practice of setting aside a reserve to pay claims, and the practice of paying a deductible before third-party coverage becomes effective.

(Bankr.E.D.Pa.1989) ("Self insurance is best compared to the familiar 'deductible' amount referenced in most insurance policies. It is common knowledge to anyone who has ever filed an insurance claim subject to same that the deductible must be exhausted before the liability of the insurer begins."); 22 APPLEMAN ON INS. 2d § 140.5 (Eric Mills Holmes, ed., 2003) at 407 n. 67 ("True self-insurance occurs when an entity retains all risks against which it might otherwise insure. This type of self-insurance is popular among governmental entities as a result of statutory immunity or costs. Another type of self-insurance occurs when an entity purchases liability insurance for a certain limit and any amount of exposure thereof is retained by the entity."); *see also Sears, Roebuck & Co. v. CIR*, 972 F.2d 858, 861 (7th Cir.1992) (stating, in context of dispute over tax treatment of insurance transaction between related corporate entities, that "'[s]elf-insurance' is just a name for the lack of insurance—for bearing risks oneself."); *Beech Aircraft Corp. v. United States*, 797 F.2d 920, 922 (10th Cir.1986) (stating, in tax case similar to Seventh Circuit's *Sears, Roebuck*, that "[s]elf-insurance is not the equivalent of insurance. If one having an insurable risk retains the risk of his own loss, there is no risk transfer, and the arrangement is self-insurance."); *In re North American Royalties, Inc.*, 276 B.R. 860, 864 (Bankr.E.D.Tenn.2002) (holding, in construing contract of insurance, that "[t]he term 'self-insured' means that the plan sponsor ... does not have insurance; it pays the expenses from its income."). These and other authorities strongly indicate that "self-insurance" is an unscientific and imprecise term, the interpretation of which varies with the context.

Our understanding of what it means to operate under a "self-insured plan" is informed by HHS regulations, to which—because of Congress' express delegation and the agency's recognized expertise in the area—we are duty-

bound to defer if they are reasonable. For purposes of the MSP statute, HHS regulations define a "plan" of insurance as including "any arrangement, oral or written, by one or more entities, to ... assume legal liability for injury or illness." 42 C.F.R. § 411.21. Inclusion of the term "oral" suggests an intent to reach informal, ad hoc arrangements in addition to traditional insurance policies; obviously, no standard insurance company issues coverage verbally. In addition, the regulations provide the following definition of a "self-insured" plan: a "[s]elf-insured plan means a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier." 42 C.F.R. § 411.50(b).

HHS has purposefully adopted a broad definition of what it means to be self-insured. For instance, the agency does not limit its definition to plans that are certified to operate as self-insurers by state insurance regulators. In enacting its inclusive definition, the agency explained that to do otherwise would enable a responsible party to elude MSP liability by paying a claim out of pocket instead of submitting the claim to its liability insurer—a mechanism not unlike the RSP compensation process here. *See* Medicare as Secondary Payer and Medicare Recovery Against Third Parties, 53 Fed. Reg. 22335, 22339-40 (proposed June 15, 1988). Of particular significance here, HHS has expressly defined a "liability insurance payment" for purposes of the MSP statute to include: "A payment to cover a deductible required by a liability insurance policy, by any individual or other entity that carries liability insurance or is covered by a self-insured plan." 42 C.F.R. § 411.50(b).

The agency's view is especially persuasive in the absence of a universally accepted and authoritative definition of "self-insured plan" which Congress might have contemplated in drafting the statute. Thus, the district

court's first articulation—that a self-insured plan connotes some type of *ex ante* arrangement to assume legal liability for medical expenses—is consistent with the regulation, to which we agree deference is due.[21] For the same reason, we agree that the district court's third articulation—that a tortfeasor's mere payment, without more, would not constitute a plan of self-insurance—is consistent with the regulations, as is its fourth—that the mere absence of insurance does not necessarily constitute a plan of self-insurance. *See* Medicare as Secondary Payer and Medicare Recovery Against Third Parties, 54 Fed. Reg. 41716, 41727 (Oct. 11, 1989) ("We note that the mere absence of insurance purchased from a carrier does not necessarily constitute a 'plan' of self-insurance."). In other words, without a plan or prearrangement, there can be no self-insured plan.[22]

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[21] To the extent that the district court meant by its term "formal" arrangement something more than that the arrangement must be *ex ante* and must be an arrangement, albeit oral, to assume legal liability or pay for medical expenses, the district court would have required more than the regulations; we see no warrant for requiring more.

[22] We see no tension between our position and that in the cases cited by Defendants, *United States v. Philip Morris, Inc.*, 116 F.Supp.2d 131 (D.D.C.2000), and *Marson v. American Tobacco Co.*, 212 F.Supp.2d 88 (E.D.N.Y.2002). In each case, the district court dismissed MSP claims seeking Medicare reimbursement from tobacco companies accused of tortiously injuring their customers. In *Philip Morris*, the Government's claim was found flawed because it merely made the conclusory allegation that the defendants were "responsible" for payment under the MSP without advancing a basis—and, specifically, without alleging the existence of a coverage plan. *Id.* at 146. In *Mason*, the plaintiffs' claim rested solely on the theory that a large corporation without insurance that was accused of inflicting a tortious injury was, by definition, operating a self-insured plan. There was no suggestion that the tortfeasor had purchased supplemental insurance and made arrangements to cover the deductible out of its own funds. *See id.* at 92. We agree with these courts to the extent that they hold that the MSP requires the existence of some sort of plan as opposed to a mere *post hoc* assumption of liability.

However, it is apparent from the foregoing quotations from the regulations that the district court's second and fifth holdings are inconsistent with the regulations. The district court's fifth holding is squarely inconsistent with the regulation's affirmative provision that a "liability insurance payment" includes "an out-of-pocket payment, including a payment to cover a deductible required by a liability insurance policy, by any entity that carries liability insurance or is covered by a self-insured plan." 42 C.F.R. § 411.50(b). There is nothing in the plain meaning of the statute which might preclude the agency's interpretation to include within the self-insured concept the commonly occurring circumstance of an individual or entity planning ahead of time to assume responsibility and liability for certain risks up to a designated amount, and to procure an insurance policy to cover the excess. As we have seen, the relevant statutory term "self-insured plan" has no precise legal meaning, seems to be interpreted by some authorities more rigidly, but is interpreted by other authorities to include precisely such a combination of self-insurance up to a certain amount with the excess to be covered by an insurance policy. Consistent with the latter authorities, common experience teaches us that planning such a combination of deductibles and insurance policies is often referred to as self-insurance. Because the statute has no unambiguous meaning in this regard, deference is due to the regulation, and the district court's contrary holding cannot stand.

We also disagree with the district court's second holding, that self-insurance requires a set-aside of funds to cover the risks assumed. Even the sparse legal authority which suggests that there usually will be a reserve for losses, also indicates that "self-insurance" has no precise legal meaning. Other authorities suggest there is no absolute need for a set-aside of funds. We see no basis in the

statute or in any well-established meaning of the statutory term "self-insured plan" to conclude that the term unambiguously requires a set-aside of funds. Thus, we look to the regulations. We conclude that an absolute requirement that funds be set aside is plainly inconsistent with the thrust of the regulations: that a self-insurance plan encompasses any arrangement, even an oral one, to assume such risks, 42 C.F.R. § 411.21; and that it encompasses the combination of deductibles and insurance policies discussed above, which in common experience often do not include a set-aside of funds. 42 C.F.R. § 411.50(b). *See also* 42 C.F.R. § 411.50(b) (defining "self-insured plan" as a plan to carry one's "own risk instead of taking out insurance," a definition requiring only a "plan" and no other formalities).[23] There being no unambiguous requirement in the statutory term "self-insured plan" that a set-aside of funds is necessary, and the same being plainly inconsistent with the thrust of the regulations, we vacate the district court's holding requiring a set-aside as a prerequisite for a "self-insured plan."

We recognize that the Fifth Circuit in *Thompson v. Goetzmann*, 315 F.3d 457 (5th Cir.2002), *opinion withdrawn and reissued as amended on other grounds*, 337 F.3d 489 (5th Cir.2003), extensively discussed the meaning of a self-insured plan in this statute, and concluded that "a 'primary plan' of 'self-insurance' requires an entity's *ex ante* adoption, for itself, of an arrangement for (1) a source of funds, and (2)

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[23] The Defendants' suggestion that the word "instead" means that "self-insurance" can exist *only* in an arrangement including no insurance is wholly without merit. Not only would that be a grudging construction of the language, it would be inconsistent with the thrust of 42 C.F.R. § 411.50(b), which contemplates a combination of insurance policies and deductibles, and with the clear weight of authority that an entity can self-insure for a designated amount and purchase coverage for liability exceeding the designated amount. *See, e.g.*, BLACK'S LAW DICTIONARY 1220 (5th ed. 1979) (explaining, in defining self-insurance, that "[a] common practice of businesses is to self-insure up to a certain amount, and then to cover any excess with insurance.").

procedures for distributing these funds when claims are made against the entity." *Id.* at 463.

We note first that we fully agree with the Fifth Circuit that the term "plan" in the statutory term "self-insured plan" clearly contemplates an *ex ante* arrangement. This is clear in both the statute and the regulation. It is probable that this is the extent of the *holding* in *Goetzmann*, and that the balance of the foregoing quotation from the Fifth Circuit case is dicta. Apparently the only issue in *Goetzmann* was whether a single, discreet, settlement by a tortfeasor with a single plaintiff whereby the tortfeasor paid the plaintiff with its own funds, without more, constituted a "self-insured plan."[24] We agree with this holding because that circumstance would not entail a "plan" or *ex ante* arrangement. It is probable therefore that what the Fifth Circuit said about setting aside funds and procedures is dicta.

We respectfully disagree with the *Goetzmann* dicta to the effect that there cannot be a self-insured plan absent a setting aside of the funds and formal procedures. We agree

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[24] The following quotations from *Goetzmann* indicate that these were the facts, thus defining the holding:

- "[W]e ... also agree with the other district courts that have concluded that an alleged tortfeasor who settles with a plaintiff is not, *ipso facto*, a 'self-insurer' under the MSP statute." *Id.* at 462.
- "[I]t is wrong for the government to contend that an entity's negotiating of a single settlement with an individual is sufficient, *in and of itself*, for such entity to be deemed as having a 'self-insurance plan.'" *Id.* at 463 (emphasis in original).
- "[N]owhere does the MSP statute mention or even suggest that an alleged tortfeasor who settles a single claim with a single plaintiff falls within the ambit of the statute's category of a 'self-insurance' plan." *Id.* at 464.
- "But [the defendant] has only negotiated a discreet settlement with a single plaintiff and paid that plaintiff accordingly. It is simply a *non sequitur* for the government to infer from 'payment responsibility' in tort a preexisting *primary plan* of self-insurance." *Id.* at 465 (emphasis in original).

with *Goetzmann* that the statutory term "self-insured plan" should be read in the context of a "primary plan." However, especially because the statutory definition of a primary plan expressly includes self-insured plans, we see nothing in that context requiring either a set-aside of funds or formal procedures. *See* 42 U.S.C. § 1395y(b)(2)(A)(i) ("In this subsection, the term 'primary plan' means ... a workman's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no-fault insurance") (parenthetical in original). We gather from the Fifth Circuit opinion that it derived its concept of the scope and limit of the term "self-insured" from the "ordinary meaning" of that term, which it derived in turn from several legal authorities, principally the Couch treatise. However, as noted above, even the legal authority relied upon by *Goetzmann* acknowledged that there was no precise legal meaning, and while some authorities suggest that a set-aside of funds and formal procedures often accompany self-insured plans, other authorities, as noted above, suggest otherwise. *Goetzmann* does not alter our conclusion that there is no precise legal meaning for the statutory term "self-insured plan" that is well-established enough to rise to the level of rendering a statutory term unambiguous.[25]

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[25] The *Goetzmann* court also rejected the Government's argument that the statute was ambiguous. Again, however, it appears likely that the court was focusing on the precise facts of the case and its narrow holding—that a discreet settlement by a single tortfeasor out of its own funds would not by itself (that is, without any prearrangement or plan) constitute a self-insured plan. This seems likely because, as discussed above, there is no precise legal meaning of the statutory term sufficiently well-established to rise to the level of rendering it unambiguous with respect to the *Goetzmann* dicta to the effect that a set-aside of funds and formal procedures are required. In other words, the statute may well be unambiguous with respect to the requirement of a plan or *ex ante* arrangement, but it is not with respect to the *Goetzmann* dicta. To the extent the Fifth Circuit intended to hold otherwise, we respectfully disagree.

Accordingly, it is appropriate to look to the regulations to which we owe deference.[26]

Applying the foregoing principles to the instant complaint, it is here alleged that "the RSP defendants were self-insured against the risk of products liability claims by breast implant recipients, and paid such claims from self-insured funds or retained earnings." The allegation that the Defendants self-insured "against the risk ... of claims" indicates that the plan or arrangement existed before the claims did, thus satisfying the requirement of an *ex ante* arrangement to assume legal liability. Moreover, there are suggestions in the record that the plan or arrangement may have included a combination of self-insurance with respect to certain amounts and the purchase of insurance policies as to other amounts, precisely the kind of combination of

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[26] We note that the *Goetzmann* court relied heavily on a questionable assumption regarding the interaction of the MSP statute and the aforementioned Medical Care Recovery Act, 42 U.S.C. § 2651. Because the express purpose of the MCRA is to impose liability upon tortfeasors to repay the Government for the reasonable value of health care furnished to a tortiously injured party, the *Goetzmann* court found that reading tortfeasor liability into the MSP "would, in effect, eliminate the need for the MCRA, or at least condemn some of Congress' language in the MCRA to the scrap heap of surplusage." *Id.* at 465. However, the *Goetzmann* reasoning does not resolve this perceived conflict, as it would itself render superfluous that portion of the MSP statute imposing liability on an entity "required or responsible" to pay under a "primary plan" of self- insurance—*i.e.*, a self-insured tortfeasor. The *Goetzmann* view would also render superfluous a substantial portion of the Government's subrogatory right conferred by the MSP statute, because establishing the liability of the patient's insurer to Medicare necessarily may require bringing a subrogation action against the tortfeasor. Moreover, *Goetzmann*'s perception of an overlap between the coverage of the MCRA and the MSP may be in error. *See Philip Morris, Inc.*, 116 F.Supp.2d at 140-44 (holding, after extensive analysis of statute's legislative history, that MCRA applies exclusively to federal health care expenditures other than Medicare, such as coverage for military personnel and their dependents); *accord In re Diet Drugs*, Nos. MDL 1203, CIV.A, 99-20593, 2001 WL 283163 at *7-*8 (E.D.Pa. March 21, 2001)

deductibles and insurance policies deemed by the regulations to constitute a self-insured plan. We readily conclude that, with respect to the self-insured plan issue, the allegations are sufficient to survive a challenge under Rule 12(b)(6).[27]

3. Can the RSP Defendants be forced to repay Medicare, when it is undisputed that they had no actual knowledge of Medicare's specific payments on behalf of particular beneficiaries?[28]

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[27] We discern no merit in the argument pressed by the Steering Committee intervenors that the RSP Defendants' payments are excepted from the reach of the MSP statute because they are not directly pegged to the amount of health care expenses incurred by the class members. Courts have uniformly concluded that a settlement agreement that includes a non-itemized element of compensation for a plaintiff's medical care is "for" medical expenses, even if the exact share or amount is indeterminate. *See Share Health Plan of Illinois, Inc. v. Alderson*, 285 Ill.App.3d 489, 220 Ill.Dec. 798, 674 N.E.2d 69, 72 (1996) (holding that HHS can recover Medicare payments from beneficiary's lump-sum settlement of tort claim "regardless of whether and how amounts are designated"); *see also Wilson v. Washington*, 142 Wash.2d 40, 10 P.3d 1061, 1067 (2000) (en banc) (finding that state Medicaid lien attached to entire amount of patient's medical malpractice settlement, not just amount earmarked for medical expenses); *accord Calvanese v. Calvanese*, 93 N.Y.2d 111, 688 N.Y>S.2d 479, 710 N.E.2d 1079, 1082 (1999). That interpretation is consistent with HHS' own understanding. *See* Medicare Program; "Without Fault" and Waiver of Recovery from an Individual as it Applies to Medicare Overpayment Liability, 63 Fed. Reg. 14506, 14514 (proposed March 25, 1998) ("Since liability payments are usually based on the injured or deceased person's medical expenses, liability payments are considered to have been made 'with respect to' medical services related to the injury even when the settlement does not expressly include an amount for medical services.").

[28] At the outset, we agree with the district court that dismissal was not warranted on the grounds that the Government failed to plead that it attempted to recoup its duplicate payments from the Medicare beneficiaries in the plaintiff class before seeking recoupment from the Defendants; it was adequately pled. We decline to address the merits of Defendants' argument that the Government is obligated to seek reimbursement first against each member of the plaintiff class before

The Government argues that the district court erred in dismissing the Government's subrogation claim pursuant to Rule 12(b)(6). As both parties and the district court understood, the Government clearly has subrogation rights to obtain reimbursement of its conditional payments. Section 1395y(b)(2)(B)(iii) provides:

> (iii) Subrogation rights
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> The United States shall be subrogated (to the extent of payment made under this subchapter for an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

In granting the Rule 12(b)(6) dismissal, the district court rejected the Government's subrogation claim, apparently either requiring proof that the RSP Defendants actually knew they were paying tort claimants whose medical expenses had already been paid by Medicare, or applying an unrealistically strict perception of constructive knowledge. At one point, the district court said that the Government had affirmatively pled facts defeating its claim, in that its complaint acknowledged that the RSP Defendants "did not ascertain" whether any of the tort claimants to be paid had actually received Medicare benefits. We reject this ground without need for further discussion; in effect, the district court required actual knowledge, and we hold that constructive knowledge is sufficient. Our discussion henceforth will focus on constructive knowledge.

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pursuing reimbursement from the RSP Defendants, because the issue is not necessary to our holding, and because the issue was inadequately addressed by the district court and inadequately briefed on appeal. The Defendants are free to assert this argument on remand, and the district court should address it anew after appropriate development of the record and briefing with respect to the agency's policies and practices, and with respect to the relevant statutes, regulations, and other authorities.

We presume that Congress legislates against the backdrop of established principles of state and federal common law, and that when it wishes to deviate from deeply rooted principles, it will say so. *See United States v. Texas*, 507 U.S. 529, 534, 113 S.Ct. 1631, 1634-35, 123 L.Ed.2d 245 (1993) ("Statutes which invade the common law ... are to be read with a presumption favoring the retention of long-established and familiar principles, except when a statutory purpose to the contrary is evident. In such cases, Congress does not write upon a clean slate. In order to abrogate a common-law principle, the statute must speak directly to the question addressed by the common law.") (internal quotes and citations omitted). It is well established at common law that a tortfeasor that pays a settlement to a claimant with knowledge—*actual or constructive*—that another entity has a subrogation claim against the proceeds is not insulated from suit by the subrogee by virtue of the incorrect payment. *See Dadeland Dodge, Inc. v. American Vehicle Ins. Co.*, 698 So.2d 929, 931 (Fla.Dist.Ct.App.1997) (holding that tortfeasor that has constructive knowledge of insurer's perfected right of subrogation cannot rely on insured's release to preclude insurer's claim for reimbursement); *accord State Farm Fire & Cas. Co. v. Pacific Rent-All, Inc.*, 90 Hawai'i 315, 978 P.2d 753, 770 (1999); *Aetna Cas. & Surety Co. v. Norwalk Foods, Inc.*, 125 Misc.2d 986, 480 N.Y.S.2d 851, 852 (1984); *see also Poole Truck Line, Inc. v. State Farm Mut. Auto. Ins. Co.*, 163 Ga.App. 755, 294 S.E.2d 570, 571-72 (1982) (because state law makes no-fault automobile coverage mandatory, tortfeasor can be charged with constructive knowledge that motorist carried insurance and that motorist's insurer had a statutory right of subrogation, thus precluding tortfeasor from invoking its settlement with injured motorist to bar insurer's subrogation claim).

In a case involving the Government's subrogation rights under this same statutory provision, the D.C. Circuit has held that a party, standing in the shoes filled by the RSP Defendants in this case, can avoid reimbursing Medicare under the instant statutory provisions only if its payment to the wrong party was made without knowledge (either actual or constructive). *HIAA*, 23 F.3d at 418 ("If a third party payor wants to avoid having to make two payments for the same service, it should refrain from paying someone whom it knows or should know that HCFA already has paid."). Further defining the content of constructive knowledge in the instant context, the D.C. Circuit cited with approval the agency's interpretation that constructive knowledge is satisfied when the third-party payor has in its possession direct information that Medicare has made a conditional payment, or has in its possession information necessary to draw the conclusion that Medicare has made such a payment.[29] The D.C. Circuit interpreted the latter reference to mean that third-party payors would be expected to draw certain inferences based on published Medicare procedures. *Id.*

We believe that the constructive knowledge standard is fully consistent with the intent of the MSP statute, and indeed necessary if the statute is to fulfill its purpose. The overriding purpose of the MSP statute was to allocate

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[29] The *HIAA* definition of constructive knowledge is essentially identical to that proffered by Defendants from the affidavit of HHS administrator Paul J. Olenick, which the Government submitted in *HIAA* as its statement of when HHS will consider an insurer to have the requisite knowledge to trigger liability under 42 C.F.R. § 411.24(i)(2). *See* Def. Ex. B ("A third party payer 'learns' of a Medicare conditional primary payment when it receives information which makes it aware, or should make it aware, that Medicare has made a conditional primary payment. This would be the case when the third party payer receives direct information that Medicare has made a conditional payment *or* when it receives the information necessary to draw the conclusion that Medicare has made a primary payment.") (emphasis in original).

primary responsibility for the payment of claims to private insurance, where available.

Between two sources of coverage, the insurer that pays second is in the superior position to prevent an erroneous or misdirected payment. The first payer can avoid such an outcome only by refusing to pay at all. Congress foreclosed that option in 42 U.S.C. §§ 1395y(b)(2)(A) and (b)(2)(B) by providing for Medicare to pay first where payment from the primary insurer was not reasonably forthcoming. When Medicare pays, therefore, it is paying "in the dark"—it does not know, and *cannot* know, whether someone else will pay.[30] By contrast, when the primary insurer later pays, Medicare's prior payment will normally be a matter of ascertainable fact.

In light of the well-established common law of subrogation, consistent with the purposes of the MSP statute, and following the D.C. Circuit, we hold that either knowledge or constructive knowledge is sufficient. Thus, if the RSP Defendants had either knowledge or constructive

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[30] HHS and Congress have repeatedly flagged Medicare's inability to ascertain the existence of alternative sources of coverage as a weakness in the secondary payer program. *See, e.g.*, Dept. of Health and Human Serv., Office of the Inspector Gen. ("HHS IG"), Survey of Medicare Payments to Workers' Compensation Recipients in the State of Florida, No. A-04-01-07003 (January 2003) at 6 ("Unfortunately, the system as currently structured does not provide a standard procedure that ensures that Medicare is informed of all [workers' compensation] settlements"); HHS IG, Medicare Prepayment Review: MSP Procedures at Carriers, No. OEI-07-89-01683 (August 1991) at 2 (citing estimate that, based on random sampling of processed by private contractors, "Medicare lost in excess of $600 million in FY 1988 due to unidentified primary payment sources"). Overlapping coverage is particularly difficult to detect where, as here, the Medicare payment and the insurance payment go to different recipients (Medicare's to the doctor or hospital, and the alleged tortfeasors' directly to the patient). In light of this well-recognized weakness, it is therefore reasonable for the agency to interpret the MSP, and Congress' subsequent revisions of it, as imposing the risk of loss on the alternative payer for failing to determine whether Medicare has already paid for the same service.

knowledge that some of the recipients of the funds they were paying out had received breast implant-related medical treatment for which Medicare already paid, then the RSP Defendants would be liable to reimburse the Government pursuant to § 1395y(b)(2)(B)(iii).

We need not at this early stage of the litigation attempt to define the precise scope of the constructive knowledge that will trigger liability, because we conclude that the Government's allegations in that regard survive Rule 12(b)(6).[31] The Government has alleged that the RSP Defendants structured the settlement in a manner so as to avoid learning any identifying information about the class members, including their Medicare eligibility. A party that willfully blinds itself to a fact, as the Complaint here alleges occurred, can be charged with constructive knowledge of that fact.[32] *See Williams v. Obstfeld*, 314 F.3d 1270, 1278

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[31] We note that the Federal Rules provide that the defendants' knowledge is an element that "may be averred generally," thus eschewing the particularity standard that applies to other mental-state elements (fraud, mistake) under Rule 9. *See* Fed.R.Civ.P. 9(b).

[32] We need not at this stage decide the significance of the facts that might be developed in this regard. However, it is clear that a party should not be able to avoid constructive knowledge and shield itself from statutory liability by consciously avoiding information which would constitute constructive knowledge and result in liability. In addition to facts that might be developed in this regard on remand, the district court might also address the relevance and significance of knowledge in fact obtained during the claims process, and whether such knowledge should be imputed to the RSP Defendants or whether they should be deemed to have consciously avoided same. At this early stage, and without development of the relevant facts, analysis by the district court, or adequate briefing from the parties, we decline to address this issue further.

In this regard, the parties have discussed whether an entity standing in the shoes of the RSP Defendants has a duty to investigate for the benefit for the Government to discover Medicare's involvement. The discussion of the parties revolved around 42 C.F.R. § 411.25(a) ("If a third party payer learns that [HHS] has made a Medicare primary payment for services for which the third party payer has made or should have made

(11th Cir.2002) (stating in context of civil RICO action that "[u]nder the doctrine of willful blindness or deliberate ignorance, which is used more often in the criminal context than in civil cases, knowledge can be imputed to a party who knows of a high probability of illegal conduct and purposely contrives to avoid learning of it."); *Commodity Futures Trading Comm'n v. Sidoti*, 178 F.3d 1132, 1136-37 (11th Cir.1999) (holding, in context of commodities fraud action, that "the element of knowledge may be inferred from deliberate acts amounting to willful blindness to the existence of fact or acts constituting conscious purpose to avoid enlightenment."). The Complaint therefore sufficiently alleges constructive knowledge, despite the Government's concession that the Defendants did not

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primary payment, it must give notice to that effect to the Medicare intermediary or carrier that paid the claim."). In light of our decision that the Government's allegations survive Rule 12(b)(6), and in light of the discovery that will be available to the Government on remand that may reveal to the Government any information that investigation by the Defendants could have yielded, thus possibly mooting the duty-to-investigate issue, we decline to address it at this stage. To the extent that the district court's discussion (*see In re Silicone Gel*, 174 F.Supp.2d at 1257) constitutes a holding that Medicare cannot interpret to require an insurer to inquire into the existence of a prior Medicare payment, we note that the district court did not address whether the agency had interpreted its regulation, or the significance thereof. *See, e.g.*, Medicare Program; Medicare Secondary Payment, 59 Fed. Reg. 4285, 4286 (Jan. 31, 1994) (explaining the statute and regulations concerning third-party payors with primary obligations to which Medicare is secondary, and suggesting pursuant to 42 C.F.R. § 411.25 that where there has been delay in paying by the primary obligor, it should assume that Medicare made a conditional payment: "A beneficiary who is eligible for Medicare files a claim for primary payment with a third party payer, the claim is denied, the beneficiary appeals, and the denial is reversed. (The third party payer should assume that Medicare made a conditional primary payment in the interim.)"). If the duty to investigate issue should become a live one on remand, then the district court should address the issue afresh conducting an appropriate analysis, *e.g.*, ascertaining any relevant agency interpretation and determining the extent of *Chevron* deference, if any.

acquire actual knowledge of Medicare's conditional primary payments.[33]

For all of the foregoing reasons, we conclude that the Government's allegations of constructive knowledge are sufficient, and the Government's subrogation claim under § 1395y(b)(2)(B)(iii) survives the Rule 12(b)(6) challenge.[34]

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[33] In responding to the motion to dismiss, the Government asked the district court for leave to amend its Complaint to plead knowledge with more detail if the court were to find that knowledge was a required element at the pleading stage. The district court denied that motion, having found that the Government had no viable claim under the MSP regardless of how it was pled. Because we reverse the district court's legal determination as to the viability of the Government's case, the district court's reason for denying leave to amend is no longer valid and that denial is accordingly vacated.

[34] The text of Part III.B(3) of this opinion has focused only on the Government's § 1395y(b)(2)(B)(iii) subrogation claim for double payment (relating to the primary obligor's liability to reimburse Medicare even though it has already paid the Medicare beneficiary). In its brief on appeal, the Government also argued, in somewhat summary fashion, that in such situation it also has a direct cause of action for double payment pursuant to § 1395y(b)(2)(B)(ii), and that the "direct action for double payment" is not conditioned upon a determination that the primary obligor paid the Medicare beneficiary even though it knew or should have known that Medicare had already covered relevant expenses. In other words, the Government argues that § 1395y(b)(2)(B)(ii) creates a strict liability "direct cause of action for double payment." We note that the D.C. Circuit in *HIAA*, 23 F.3d at 417, apparently rejected this argument, inferring from the language of the statute that the Government had a claim against the "required or responsible" entity until that entity made payment, and thereafter had a claim against the person who received such payment. *See* 42 U.S.C. § 1395y(b)(2)(B)(ii) ("The United States may bring an action against any entity which is required or responsible under this subsection to pay with respect to such item or service ... under a primary plan ... or against any other entity (including any physician or provider) that has received payment from that entity with respect to the item or service"). The district court, following the D.C. Circuit, rejected the Government's argument on the same ground.

We need not in this case decide whether the inference drawn by the D.C. Circuit and the district court is the only reasonable interpretation of the statute, because we reject the Government's argument in this case on other grounds. The only support for its position proffered by the

Government in this case is 42 C.F.R. § 411.24(i), which provides in relevant part:

> (i) *Special rules.* (1) In the case of liability insurance settlements and disputed claims under employer group health plans and no-fault insurance, the following rule applies: If Medicare is not reimbursed [by the recipient of the insurance payment] ... the third party payer must reimburse Medicare even though it has already reimbursed the beneficiary or other party.
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> (2) The provisions of paragraph (i)(1) of this section also apply if a third party payer makes its payment to an entity other than Medicare when it is, or should be, aware that Medicare has made a conditional primary payment.

However, we do not believe that the regulation supports the Government's litigation position of strict liability without regard to knowledge or constructive knowledge. The regulation indicates that a third-party payor who pays the patient is still liable for a "double payment" to Medicare in two situations: (1) when the source of the third-party payment is a liability insurance settlement or a disputed claim under group insurance or no fault coverage, or (2) when other circumstances give the third-party payor knowledge or constructive knowledge of Medicare's prior payment. Both the language of the regulation and the explanation provided by HHS in promulgating the regulation suggest that the distinction between subparagraphs (1) and (2) is not between strict liability and liability only if there is knowledge or constructive knowledge. Rather, the use of the term "disputed claims" in subparagraph (1) indicates that HHS was singling out cases in which the third party would not pay until after considerable delay—which delay, coupled with the existence of the MSP statute and regulations, HHS apparently deems to be sufficient to constitute constructive knowledge that Medicare will have made a conditional payment. The explanation provided by HHS in promulgating its final version of the rule focuses upon constructive knowledge or "awareness," and bears out this interpretation:

> We agree that when an employer group health plan (EGHP) or no-fault insurer routinely pays primary benefits on behalf of a Medicare beneficiary without knowledge of Medicare's primary payment, the insurer has acted responsibly and should not be liable for reimbursing HCFA if HCFA is unable to recover from the party that received the insurer's primary payment. However, if a third party pays an entity other than Medicare even though it was, or should have been, aware that Medicare had made a conditional primary payment, the third party must reimburse Medicare .... Liability insurers should be aware of Medicare involvement, and therefore should not pay a claim without first checking to find out if

4. Does the MSP's "double damages" provision apply to a payer that has paid the beneficiary but fails to promptly pay the Government's "double payment" reimbursement claim?

Medicare's right of action for double damages originates in § 1395y(b)(2)(B)(ii), entitled "Action by United States." It provides that "the United States may bring an action

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Medicare has made conditional payments. The EGHP or no-fault insurer should be aware that, if the claim was disputed, Medicare may have made a conditional payment.

Medicare as Secondary Payer and Medicare Recovery Against Third Parties, 54 Fed. Reg. 41716, 41721 (Oct. 11, 1989) (emphasis added). Thus, neither the language of the regulation nor the official explanation at promulgation supports the Government's assertion of strict liability in this case. Rather, the regulation and official interpretation indicate that constructive knowledge is required.

Having rejected the Government's only authority for imposing strict liability with respect to a "direct cause of action for double payment" under 1395y(b)(2)(B)(ii), we conclude that this case should proceed with the law of the case being that the Government must prove at least constructive knowledge to prevail in its claim for double payment under either § 1395y(b)(2)(B)(ii) or § 1395(b)(2)(B)(iii).

As we noted in the text with respect to our discussion of the subrogation claim for double payment, we need not at this early stage of the litigation define the precise scope of constructive knowledge that will trigger liability, because constructive knowledge in the form of willful blindness has been amply pleaded in this case. Moreover, the contours of constructive knowledge were not adequately addressed by the district court and have not been adequately addressed in the briefs on appeal.

Although the district court opinion, the briefs on appeal, and this opinion have focused on the "double payment" claim, nothing in this opinion precludes the district court on remand from entertaining a Government claim pursuant to the "direct action for single payment," *i.e.*, where the RSP Defendants have not yet paid or the RSP claimants have not yet received such payment. *See* 42 U.S.C. § 1395y(b)(2)(B)(ii) ("In order to recover payment under this subchapter for ... an item or service, the United States may bring an action against any entity which is required or responsible ... to pay with respect to such item or service ... under a primary plan ... or against any other entity (including any physician or provider) that has received payment from that entity with respect to the item or service") (parenthetical in original).

against any entity which is required or responsible under this subsection to pay with respect to such item or service (or any portion thereof) under a primary plan (and may, *in accordance with paragraph (3)(A)* collect double damages against that entity)" (emphasis added). Paragraph (3)(A), which the provision incorporates, then establishes a private cause of action for double damages "in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with such paragraphs (1) and (2)(A)."[35] There is no dispute that, under subparagraph (2)(B)(ii), the Government can sometimes bring a double damages action. The only disagreement is whether the qualifier "or appropriate reimbursement" empowers Medicare to recover double damages from an entity that has made its primary payment to the beneficiaries but fails to make a duplicate payment to Medicare on demand.

The district court ultimately rejected the Government's double damages claim on the same rationale that it dismissed its single damages claim. However, we have already reversed the district court's holding with respect to the Government's single damages claim. *See* Part III.B., *supra*. Accordingly, we also reverse the district court's dismissal of the Government's double damages claim and vacate the district court's rulings in that regard. While we expect the district court on remand to address the double damages claim on a clean slate, we offer a few comments to call attention to several pertinent matters.

We note that the statute is not clear as to when the Government is entitled to more than single damages. The statute gives the Government the right to seek double damages "in accordance with paragraph (3)(A)," *see* 42

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35 Paragraph (1) pertains to the responsibility of group health plans to assume primary responsibility for the coverage of their Medicare-eligible beneficiaries, and is not implicated here.

U.S.C. § 1395y(b)(2)(B)(ii). Paragraph (3)(A) in turn establishes a private cause of action for double damages if a primary plan "fails to provide for primary payment (or appropriate reimbursement) in accordance with ... paragraphs (1) and (2)(A)." Paragraph (1) prohibits an employer group health plan from offering lesser coverage to employees over 65 or their spouses on the basis of their Medicare eligibility. Paragraph (2)(A) defines which sources of outside coverage will be primary with respect to Medicare. The pivotal ambiguity is in the term "reimbursement," which can plausibly refer either to the insurer's obligation to reimburse Medicare (the Government's view), or the insurer's duty to reimburse the injured party for out-of-pocket medical expenses (the Defendants' view), or both.

The pertinent regulations to which we owe deference are codified at 42 C.F.R. §§ 411.24(c)(1) and (c)(2). In these regulations, HHS draws a distinction between claims in which the insurer willingly repays Medicare versus those in which Medicare is forced to litigate. Only in the second category of cases, according to the regulations, will the Government demand double damages. The Government cited the regulations in its Complaint, but did not rely on § 411.24(c) in its briefs to the district court or here. The district court did not pass on whether the regulations were authorized by and consistent with the statute, nor—so far as we can find—has any other federal court.

Another matter to which the district court should give attention is whether the proof required to establish entitlement to double damages is the same as that required for single damages, and if that seems suggested by the statutory language, whether it makes sense in light of the statutory structure and purpose. Finally, if the same proof or standard is suggested for both single and double damages, the court should consider whether that would be

inconsistent with the common-law principle that an award of multiple damages usually requires a heightened showing of wrongful intent.

5. Can either the MSP Defendants or the Escrow Agent be sued under the MSP as an entity that "received payment" from a primary plan?

The Government argues that the MSP Defendants can be sued under § 1395y(b)(2)(B)(ii) as entities that "received payment" from a primary plan, on the basis that they received payment from their liability carriers. The Government further argues that the Escrow Agent is reachable under the same provision because it received payment from the MSP Defendants and/or their insurance companies. The district court dismissed both contentions on the basis that, under the common understanding of the term "received," the statute covers only the ultimate recipient of the payments—not someone merely handling the money as a conduit.

The pertinent statutory passage provides that "the United States may bring an action against any entity which is required or responsible under this subsection to pay ... or against any other entity (including any physician or provider) that has received payment from that entity with respect to the item or service[.]" 42 U.S.C. § 1395y(b)(2)(B)(ii). Under the doctrine of *ejusdem generis*, "when an enumeration of specific things is followed by some more general word or phrase, then the general word or phrase will usually be construed to refer to things of the same kind or species as those specifically enumerated." *City of Delray Beach v. Agricultural Ins. Co.*, 85 F.3d 1527, 1534 (11th Cir.1996); *see also Snapp v. Unlimited Concepts, Inc.*, 208 F.3d 928, 934 (11th Cir.2000) ("We must interpret 'a general statutory term ... in light of the specific terms that surround it.'") (*quoting Hughey v. United States*, 495 U.S.

411, 419, 110 S.Ct. 1979, 1984, 109 L.Ed.2d 408 (1990)).[36] Applying *ejusdem generis* here, we can assume that Congress intended the term "any other entity" to be understood with reference to "physician" and "provider," and to encompass only entities of like kind.

The agency's implementing regulation, 42 C.F.R. § 411.24(g), lists as examples of entities liable as recipients: "a beneficiary, provider, supplier, physician, attorney, State agency or private insurer that has received a third party payment." This list is broader than that furnished by the statute, but even the agency's examples all are entities that would be receiving payment under a claim of right or entitlement to retain it.

The Escrow Agent clearly is not of like kind to a doctor or provider. The uncontested evidence is that the Escrow Agent acts in a purely ministerial role serving the district court. All of the discretionary decisions about which claims to honor are made by the Claims Office, which is a separate entity.[37] The Escrow Agent is limited to petitioning the court if he wishes to refrain from making a payment. His only real power appears to be in making sure that the RSP Defendants continually contribute enough money to sustain

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[36] In *Snapp* we examined a provision in the Fair Labor Standards Act, 29 U.S.C. § 216(b), providing that "[a]ny employer who violates the provisions of section 215(a)(3) of this title shall be liable for such legal or equitable relief as may be appropriate ... including without limitation employment, reinstatement, promotion, and the payment of wages lost and an additional equal amount as liquidated damages." Applying the principle of *ejusdem generis*, the *Snapp* court held that punitive damages were entirely unlike the remedies enumerated in the statute, all of which were intended to compensate the plaintiff rather than punish the defendant; therefore, we held that punitive damages were not intended by Congress as part of the remedial scheme. *Id.* at 935.

[37] When a potential class member appeals the denial of her claim, the appeal goes first to the Claims Administrator and then to the district court, not to the Escrow Agent.

the settlement fund, which does not equate to discretion over the payment of claims.

In *HIAA*, the D.C. Circuit invalidated as exceeding HHS' statutory authority the former 42 C.F.R. § 411.24(e), which provided that Medicare's direct right of action under 42 U.S.C. § 1395y(b)(2)(B)(ii) extended to a third-party administrator of an employer self-insurance plan as an entity charged with "making primary payment." The court held that the statute contemplated liability only for parties who were responsible *for payment*, not merely responsible for the ministerial function of *making* the payment. The court likened HCFA's interpretation to extending liability to the bank on which the health insurers' benefit checks were drawn, even though the bank obviously had no discretion over whether and to whom payment was made. *Id.* at 416-17.

In 1996, Congress amended the MSP, reinstating in part provisions struck down by *HIAA*. Specifically, the 1996 amendments to § 1395y(b)(2)(B)(ii) provide that the Government "may not recover from a third-party administrator under this clause in cases where the third-party administrator would not be able to recover the amount at issue from the employer or group health plan and is not employed by or under contract with the employer or group health plan at the time the action for recovery is initiated[.]" Although this legislation evidences congressional intent to reach third-party administrators under certain circumstances, it does not assist the Government here, since it is conceded that Gentile is an agent of the court, neither employed by nor under contract with the RSP Defendants.[38]

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38 The only case the Government cites supporting its position that a trustee-like entity could be regarded as having "received" the money it handles is *King v. United States*, 379 U.S. 329, 85 S.Ct. 427, 13 L.Ed.2d 315 (1964). *King* arose under an entirely different statutory scheme—it

Finally, any analogy between the Escrow Agent and a third-party administrator is inapt. While it is true that Congress has clarified that HHS can sometimes lodge a claim against a third-party administrator even where the administrator is merely a "pass-through" who is not ultimately responsible for paying the claimant, the potential analog to a third-party administrator in our case is the Claims Office, not the Escrow Agent. A self-insurer hires a third-party administrator to do what the Claims Office is doing here: to decide who gets paid and how much. The Government, however, did not name the Claims Office or its administrator as defendants. Consequently, the district court was correct in dismissing Count VI against the Escrow Agent.[39]

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evolved out of a Chapter 11 bankruptcy proceeding. The court-appointed "distributing agent" in that case (significantly, the president of the bankrupt company as opposed to a disinterested functionary) was held to be personally liable for having depleted the bankruptcy estate by paying private claims before paying the Government, because of his considerable authority to object to the way the estate was distributed. The *King* court strictly limited the holding to its facts. *See id.*, 379 U.S. at 339, 85 S.Ct. at 432 ("We are not prepared to articulate any general rule defining the responsibility of distributing agents to make and press ... objections [to a plan of distribution]. We hold only that King, on the facts of this case, did have such a responsibility. As president of the debtor corporation he must have been aware of the Government's potential claim[.]"). It is a considerable stretch to apply such a limited, fact-specific holding to our entirely different context.

[39] From the comments of counsel for the Government at oral argument, and from the parties' discussion at the hearing before the district court on May 15, 2000, we discern that the Government's main interest in laying a claim for reimbursement against the Escrow Agent was to keep the Agent in the case as a party so that he would be subject to any order granting appropriate injunctive relief. We note that Count VII, seeking injunctive relief against the Escrow Agent, is still alive, *see* Part III.B.(6), *infra*. Thus, pending further developments in the district court on remand, the Escrow Agent remains a party. In any event, we believe that the district court would retain the ability to direct the Escrow Agent's management of the settlement funds as required to preserve the Government's rights, whether or not substantive claims

We reach a different conclusion, however, as to the RSP Defendants. Section 411.24(g) of the regulations lists an "insurer" as an example of a party that may be liable as having received payment. As we have seen, the MSP treats self-insured entities as "insurers." The structure of the underlying transaction here—the RSP manufacturers paid into the settlement fund out of their own earnings, then submitted claims to their liability carriers for partial reimbursement—is not unlike that commonly occurring in which one insurance carrier re-insures or carries excess liability coverage, thus making it both a payer (to its insured) and a recipient (in relation to its re-insurer). We believe that is the sort of arrangement HHS contemplated in including insurers and state agencies among the class of parties that could be liable on the basis of receiving payment.[40] The RSP Defendants do not argue that the regulation is invalid, and we see nothing unreasonable in the regulation as applied to this case.

The record is devoid of detail about the role of the Defendants' liability insurance carriers. If our understanding is correct—that the RSP companies initially financed the settlement, then filed claims with their insurers, which will provide reimbursement based on their independent evaluation of the class members' claims—then the district court's description of the RSP Defendants as mere intermediaries between their insurance companies and the class members is not accurate. Rather, it appears that the RSP Defendants would keep the insurance companies' payments to reimburse them for what they paid the class members. Consequently, it is conceivable that the

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remain against him, either pursuant to the court's supervisory powers, or by retaining him or joining him to afford appropriate relief to the parties.

[40] The references to "a State agency" and "a private insurer" in § 411.24(g) indicate that HHS believes a party can be a recipient of payment even if all it is receiving is reimbursement for its own prior payments, rather than (as with a doctor) a fee for services rendered.

Government could prove that the RSP Defendants "received payment" from a third party within the meaning of the statute.

6. Does the Government have a claim under the MSP statute for declaratory and injunctive relief (Counts V and VII)?

In addition to damages, the Government's Complaint sought: (1) a declaratory judgment that the RSP Defendants are liable under the MSP to reimburse Medicare for past payments to breast implant patients, and are obligated to provide Medicare with notice of all payments to Medicare beneficiaries, and (2) an injunction prohibiting the Escrow Agent from making disbursements to Medicare patients pending resolution of the Government's claims, and to compel disclosure of identifying information concerning all past or contemplated settlement payments to Medicare beneficiaries.

Although both declaratory relief and injunctive relief may be unnecessary depending on further developments on remand, the entire landscape of this case has changed with our disposition of this appeal. We prefer for the district court to evaluate the need for such relief in the first instance in light of the new landscape.[41] We therefore vacate the dismissal of the Government's claims for declaratory and injunctive relief, which will enable the district court to fashion the most appropriately tailored remedy.[42]

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[41] For example, it is not beyond doubt that there may be need of injunctive relief to afford complete relief to the parties.

[42] We suspect that most of the Government's requests for injunctive relief will be effectively moot in any event. Because we reinstate the bulk of the Government's substantive claims for damages, discovery can now proceed and the Government will thereby gain access to the information it sought by way of a declaratory or injunctive order. In light of this likely mootness, we do not address the Defendants' arguments regarding

IV. CONCLUSION

We reverse the district court's dismissal of Counts I, II, III and IV as they regard the RSP Defendants. We also vacate the district court's dismissal of the Government's requests for declaratory and injunctive relief in Counts V and VII. Finally, we affirm the district court's dismissal of Count VI, which sought reimbursement from the Escrow Agent as an entity receiving payment.[43]

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED.

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whether, and to what extent, the MSP statute allows for declaratory or injunctive relief as a remedy.

[43] As noted, the Government has abandoned Counts VIII and IX.

UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION

Master File No. CV-92-N-10000-S,
CV-00-N-0837-S, (MDL 926)

In re: Silicone Gel Breast Implants Products Liability Litigation (MDL 926)

United States of America,

v.

Baxter International, Inc., et al.

September 26, 2001, Decided

Before NELSON, District Judge.

OPINION

Memorandum of Opinion

EDWIN L. NELSON, District Judge:

The United States[1] filed this action on March 30, 2000, against Baxter International Inc., Baxter Healthcare Corporation, Bristol-Myers Squibb Company, Minnesota Mining & Manufacturing Co., Union Carbide Chemical & Plastics Co., Union Carbide Corporation (collectively, the "RSP Defendants"), and Edgar C. Gentle, III, in his official

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[1] The United States brought this action on behalf of the Department of Health and Human Services, Health Care Financing Administration ("HCFA") the Indian Health Service ("IHS"), the Department of Defense ("DoD"), and the Department of Veterans Affairs ("VA").

capacity as the Escrow Agent for the Settlement Fund established in *In re Silicone Gel Breast Implant Products Liability Litigation* (MDL 926), No. CV-92-N-10000-S (N.D. Ala.)(the Escrow Agent).

The matter is presently before the Court on motions of the RSP Defendants, the Escrow Agent, and intervenor Plaintiffs' Steering Committee (the "PSC")[2], to dismiss the complaint pursuant to Fed.R.Civ.P. 12(b)(6). On September 14, 2000, the Court heard oral arguments on the motions and provisionally granted the PSC's motion to intervene.[3] For the reasons discussed below, the motions to dismiss will be granted in all respects.

I. STANDARD OF REVIEW.

A plaintiff need only set forth "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed.R.Civ.P. 8(a). The complaint is sufficient if it gives a defendant notice of the claims by which the plaintiff seeks to hold the defendant liable. A plaintiff is not required "to set out in detail the facts upon which he bases his claim." *Conley v. Gibson*, 355 U.S. 41, 47, 78 S.Ct. 99, 2 L.Ed.2d 80. 99 (1957). Accordingly, "the threshold of sufficiency that a complaint must meet to survive a motion to dismiss for failure to state a claim is exceedingly low." *Quality Foods de Centro America v. Latin American Agribusiness Dev. Corp.*, 711 F.2d 989, 995 (11th Cir.1983). "The purpose of a Rule 12(b)(6) motion is to test the facial sufficiency of the statement of claim for relief." *Brooks v. Blue Cross & Blue*

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[2] The PSC is a committee appointed by this court in 1992 to coordinate discovery and other pretrial proceedings on behalf of the various plaintiffs in MDL 926. MDL Revised Case Management Order No. 5 (Sept. 15, 1992) at ¶ 7(b).

[3] Upon due consideration, the Court finds the PSC Motion to Intervene is due to be granted. The PSC has a substantial interest in the United States' claims that the RSP Settlement Fund and the Common Benefit Fund are responsible for paying the United States' claims out of fund monies.

Shield, 116 F.3d 1364, 1368 (11th Cir.1997). A court should only grant such a motion "when the movant demonstrates 'beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief.'" *Harper v. Blockbuster Entertainment Corp.*, 139 F.3d 1385, 1387 (11th Cir.1998) (quoting *Conley*, 355 U.S. at 45-46, 78 S.Ct. 99).

In reviewing a defendants' Rule 12(b)(6) motion to dismiss, the Court must "take the material allegations of the complaint and its incorporated exhibits as true ... and liberally construe the complaint in favor of the plaintiff." *Burch v. Apalachee Community Mental Health Servs., Inc.*, 840 F.2d 797, 798 (11th Cir.1988) (*en banc*), *aff'd sub nom. Zinermon v. Burch*, 494 U.S. 113, 110 S.Ct. 975, 108 L.Ed.2d 100 (1990). The Court's Rule 12(b)(6) review "is limited primarily to the face of the complaint and attachments thereto." *Brooks*, 116 F.3d at 1368.

When this court is called upon to construe a statute, the first question must always be whether Congress has directly spoken to the precise question at issue so that the intent of Congress is clear. *Chevron U.S.A., Inc. v. National Resources Defense Council, Inc.*, 467 U.S. 837, 842-43, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). If the statute is silent or ambiguous with respect to a specific issue, an agency's construction that is based on a permissible construction of the statute is controlling. *Id.* However, the litigation position of agency counsel that is wholly unsupported by regulations, rulings, or administrative practice is not entitled to deference. *Bowen v. Georgetown University Hosp.*, 488 U.S. 204, 211, 109 S.Ct. 468, 102 L.Ed.2d 493 (1988).

II. STATEMENT OF FACTS.

A. Scope.

The facts set forth below are based upon the allegations of the complaint and upon this court's public record subject

to judicial notice under Fed.R.Evid. 201. A court may take judicial notice of its own records in 12(b)(6) proceedings. *ITT Rayonier, Inc. v. United States*, 651 F.2d 343, 345 n. 2 (5th Cir.1981). *See also Bryant v. Avado Brands, Inc.*, 187 F.3d 1271, 1276 (11th Cir.1999) (approving practice of judicially noticing publicly filed documents with SEC on a motion to dismiss) *and Wells v. United States*, 318 U.S. 257, 63 S.Ct. 582, 87 L.Ed. 746 (1943) (judicial notice of court records is appropriate). This court's records subject to judicial notice include documents filed in *In re Silicone Gel Breast Implants Products Liability Litigation* (MDL 926), No. CV-92-N-10000-S (N.D.Ala.1992) and in *Lindsey v. Dow Corning Corp.*, No. CV-94-N-11558-S (N.D.Ala.1994). As public records, they contain facts "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." Fed.R.Evid. 201.

B. The Facts.

On June 25, 1992, the Judicial Panel on Multidistrict Litigation transferred all pending federal court actions in which the plaintiffs alleged they had been injured by silicone gel breast implants to the Northern District of Alabama. *See In re Silicone Gel Breast Implants Prods. Liab. Litig. (MDL 926)*, 793 F.Supp. 1098 (J.P.M.L.1992). In April 1994, Judge Sam Pointer, Jr.[4] of this court provisionally certified *Lindsey v. Dow Corning, et al.*, as a class action for settlement purposes under Fed.R.Civ.P. 23(b)(3). *Lindsey v. Dow Corning Corp.*, No. CV 94-P-11558-S (N.D.Ala.). By Order 27, entered on December 22, 1995, Judge Pointer approved the "Bristol, Baxter, 3M, McGhan and Union Carbide Revised Settlement Program" (the "RSP") for the *Lindsey* class.

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[4] The case was originally assigned to Chief Judge Sam C. Pointer in 1992 and was managed by him until his retirement from the bench in early April 2000. Management responsibility of the remaining cases in MDL 926 was transferred to the undersigned.

The RSP is funded by the settling MDL 926 defendants, who "pay into the fund. ... such amounts as, from time to time during the 15 year period of the program, are estimated ... to be needed ... to pay benefits ...." Order No. 27, ¶ J. The RSP's benefits to class members include a payment to defray the cost of explant surgery and additional benefits for those claimants with certain diseases or injuries. Claimants are not required to prove a causal link between their breast implants and the claimed disease or condition. *See generally*, Order No. 27.

The RSP Defendants have also entered into settlements with many plaintiffs who opted out of the *Lindsey* class action and the RSP. Compl. ¶¶ 21-22.

Under the terms of Order 27 in MDL 926, a "Common Benefit Fund" was also established. The Common Benefit Fund was and is used to compensate and reimburse counsel who provided services for the "common benefit" of the *Lindsey* class. When RSP Defendants pay settlement amounts into the RSP, they pay a six percent surcharge that is designated as the Common Benefit Fund, and held as part of the RSP fund. Plaintiffs who settle or obtain judgment in an opt-out lawsuit similarly pay 6% of the settlement amount into the Common Benefit Fund. Notice of Revised Settlement Program, ¶ 28. In Order No. 13A (December 28, 1999), the Court ordered a 2% pro-rata "rebate" of excess funds in the Common Benefit Fund and subsequent surcharge amounts have been limited to 4 percent.

The United States filed its complaint in this action more than four years after the court's approval of the *Lindsey* class settlement.[5] The United States avers it, through

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[5] The United States claims it is not subject to the defense of laches in enforcing its rights. *United States v. Summerlin*, 310 U.S. 414, 416, 60 S.Ct. 1019, 84 L.Ed. 1283 (1940); *United States v. Fernon*, 640 F.2d 609, 612 (5th Cir.1981). The United States also vigorously disputes any assertions of delay and inaction on its part.

HCFA, DoD, VA and IHS, has furnished or paid for medical care and treatment related to breast implants for claimants who were or will be compensated through the RSP. This is a suit to recover the costs of that medical care from the funds. The United States claims the defendants are liable to reimburse the government for the medical care of breast implant claimants despite the defendants' previous settlement payments to breast implant claimants.

The United States cannot sue to recover medical costs unless explicitly authorized by Congress. *United States v. Standard Oil Co.*, 332 U.S. 301, 67 S.Ct. 1604, 91 L.Ed. 2067 (1947). The United States asserts that the present suit is appropriate and authorized under the Medicare Secondary Payer statute, 42 U.S.C. § 1395y(b) and/or the Medical Care Recovery Act, 42 U.S.C. §§ 2651-2653.

III. THE MEDICARE SECONDARY PAYER STATUTE.

The Medicare Secondary Payer statute (hereinafter, the "MSP" statute) is a series of amendments designed to lower Medicare costs by making Medicare coverage secondary to coverage provided by private insurance programs. The MSP statute is codified at 42 U.S.C. § 1395y(b). When a third party payer has made or can reasonably be expected to make payment to a Medicare beneficiary, Medicare's payment is "conditional" on reimbursement to the Medicare Trust Fund. 42 U.S.C. § 1395y(b)(2)(B)(i). To ensure that the required reimbursement occurs, the United States may sue to recover conditional Medicare payments "when notice or other information is received that payment for such item has been or could be made under" a pertinent plan or policy. 42 U.S.C. § 1395y(b)(2)(B)(ii); *see also* 42 C.F.R. § 411.24(e) & (g). The defendants assert that the United States cannot bring suit under the MSP without identifying the persons who received Medicare benefits and the "items" or "services" provided by the government.

The MSP statute provides in pertinent part:

> In order to recover payments under this subchapter for such an item or service, the United States may bring an action against any entity which is required or responsible (directly, as a third-party administrator, or otherwise) to make payment with respect to such item or service (or any portion thereof) under a primary plan (and may, in accordance with paragraph (3)(A) collect double damages against that entity), or against any other entity (including any physician or provider) that has received payment from that entity with respect to the item or service and may join or intervene in any action related to the events that gave rise to the need for the item or service.

42 U.S.C. § 1395y(b)(2)(B)(ii). The statute further provides:

> The United States shall be subrogated (to the extent of payment made under this subchapter for such an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

42 U.S.C. § 1395y(b)(2)(B)(iii).

A. The Government Has Identified Neither the Medicare Recipients Nor Services It Provided for Which It Claims Reimbursement.

The defendants have asserted an overarching challenge to all of the government's MSP claims, arguing that the United States must identify the individuals who received government benefits for breast implant-related medical conditions and specify the services that were provided to those individuals.

The United States claims it need not specify the names of the individual claimants who have received Medicare benefits because it is bringing a direct, independent action

pursuant to § 1395y(b)(2)(B)(ii) rather than a subrogation action under § 1395y(b)(2)(B)(iii).

However, in Count IV, the United States claims "reimbursement as a subrogee of those Claimants who are Medicare beneficiaries and ... repayment of its conditional Medicare payments from all future disbursements from the MDL Settlement Fund and/or the Common Benefit Fund." Compl. ¶¶ 66-68. To proceed in a subrogation action, the subrogee must identify its insureds. *Zinman v. Shalala*, 67 F.3d 841, 844 (9th Cir.1995) (under the right of subrogation, HCFA has the right to "be put in the legal position of the beneficiary in order to recover from third parties who are legally responsible to the beneficiary for a loss"); *Health Care Serv. Corp. v. Brown & Williamson Tobacco Corp.*, 208 F.3d 579, 581 (7th Cir.2000). Because the United States has not identified the individual beneficiaries for whom it claims reimbursement, and apparently cannot do so, its subrogation claim asserted in Count IV must be dismissed.

The remaining MSP claims, brought as direct actions under subsection (b)(2)(B)(ii), must be dismissed for the same reasons. A direct action under subsection (b)(2)(B)(ii) permits the government to recover only what the primary provider "is required or responsible ... to pay with respect to [an] item or service" provided to the [Medicare] beneficiary. 42 U.S.C. § 1395y(b)(2)(B)(ii). Accordingly, an essential element of the government's MSP direct action against a primary payer is the proof that the primary payer is "required or responsible" to pay for "items or services" provided to a Medicare beneficiary. The relationship between the Medicare beneficiary and the primary provider is the foundation upon which the government's claim rests and no matter whether the government pursues a direct action or a subrogation action under the MSP, the government stands exactly in the beneficiary's shoes when recovering from available insurance funds. *Waters v.*

Farmers Tex. County Mut. Ins. Co., 9 F.3d 397, 400-01 (5th Cir.1993).

A complaint must show that the pleader is entitled to relief, Fed.R.Civ.P. 8(a), and a complaint based on "conclusory allegations and unwarranted deductions of fact" is subject to dismissal under Rule 12(b)(6). *South Fla. Water Mgt. Dist. v. Montalvo*, 84 F.3d 402, 408 n. 10 (11th Cir.1996). Because there is no distinction for pleading purposes between the United States' direct action and its subrogation action under (b)(2)(B)(iii), the United States must (1) identify its Medicare beneficiaries; (2) specify the medical items or services it provided; and (3) plead and prove that the defendants are "required or responsible" to make the primary payment with respect to that beneficiary and those medical items or services. *City of Birmingham v. American Tobacco Co.*, 10 F.Supp.2d 1257 (N.D.Ala.1998) (Pointer, C.J.) (suit brought pursuant to state statute providing for either direct or subrogated action required particulars about individual employees and medical services). "If the United States is unable to provide even this basic threshold information, it cannot possibly provide the additional information necessary to prove its claim, such as: the type of medical treatment provided, why the treatment was necessary, the costs of treatment ...." *In re Dow Corning Corp.*, 244 B.R. 705, 713 (E.D.Mich.1999) (Amended Opinion Regarding Cramdown on Class 15).[6]

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[6] The RSP Defendants also point out that the present proceeding subverts the administrative rights of claimants to challenge the reimbursement request and to petition the government to waive its claim. *See* 42 U.S.C. § 1395y(b)(2)(B)(iv); *Zinman v. Shalala*, 835 F.Supp. 1163, 1170-72 (N.D.Cal.1993)(fundamental principles of due process require that the Government directly inform beneficiaries of their right to seek waiver), *aff'd* 67 F.3d 841 (9th Cir.1995). The United States counters that individual beneficiaries may seek waivers, but fails to explain how the procedure would work when the individual beneficiaries are not identified and the claim is against the tortfeasor. The beneficiaries are interested parties, since a third-party payer who is required to reimburse Medicare

Accordingly, the United States' MSP claims are due to be dismissed because it must, at a minimum, identify the Medicare beneficiaries who have received benefits from the defendants.[7]

B. Fairness.

Although it does not specifically assert a claim of estoppel or waiver, the United States argues that its inability to plead the names of the Medicare recipients who received a breast implant settlement is the fault of the defendants because they structured the RSP settlement to include confidentiality provisions.[8]

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can attempt to recover its original payment from the recipient. *HIAA v. Shalala*, 23 F.3d 412, 418 n. 4 (D.C.Cir.1994).

[7] *And see United States v. Philip Morris, Inc.*, 153 F.Supp.2d 32, 37-38 (D.D.C.2001) (the government's independent right to recover under the MCRA, 42 U.S.C. § 2651(a), is not independent in the sense that it requires the government to show the existence of persons injured by a tortfeasor, and as existence of legally injured person is a prerequisite for and an essential element of the government's MCRA claim, it must be pleaded in the complaint). This court agrees that the government cannot proceed with its MCRA claims until it pleads the names of the injured parties for whom it claims to have provided medical care.

[8] To the extent the United States has raised a factual question regarding the RSP Defendants' intent, the court will assume the defendants intended to avoid obtaining knowledge about the identities of the claimants for the purpose of this motion to dismiss. The court observes that, unless the United States establishes that the defendants were required by statute to collect such information, any reluctance on the part of the RSP defendants to assume the responsibility for obtaining knowledge is not relevant to the United States' claims. Furthermore, there is no factual basis asserted in the complaint for the United States' argument that the defendants inserted confidentiality provisions in the RSP settlement for the explicit purpose of cheating the government of its reimbursements. The notion defies common sense in the context of this litigation, which involved sensitive and confidential medical issues for the plaintiff class. Moreover, like all class settlements, this settlement was not the unilateral product of the defendants but was the result of input from all of the parties and intensive judicial oversight. Fed.R.Civ.P. 23(e).

The court is not sympathetic to the United States' attempt to make the defendants responsible for its inability to comply with the requirements of the MSP statute or with the pleading requirements of Fed.R.Civ.P. 8(a). The court observes that the United States was not limited to its statutory remedy in this case since the RSP claims administrator, who is a special master appointed by this court, has established procedures to process insurance reimbursement claims like the one now asserted by the United States. The United States eschews the administrator's procedures, arguing it is not bound by the settlement terms and its statutory rights cannot be altered by the court.

The court heartily agrees with the proposition that it cannot force the United States, or any other insurer, to make its claim through the claims office. However, the availability of an alternative avenue by which the government could have obtained the relief it seeks certainly diminishes any claim that the government should obtain any special relief from the statutory requirements. Since the United States has elected to pursue its claim via the litigation procedures set out by statute, it will not now be heard to complain about its inability to comply with the terms of those procedures.

IV. THE MSP CLAIMS AGAINST THE RSP DEFENDANTS—COUNTS I, II, III AND V.

A. Counts I and II—Claims Brought Pursuant to the "Double Payment" Regulation.

The so-called "double payment" regulation provides, in pertinent part:

> (i) Special rules.
>
> (1) In the case of liability insurance settlements and disputed claims under employer group health plans and no-fault insurance, the following rule applies: If Medicare is not reimbursed [by the

> beneficiary or other party receiving payment] as required by paragraph (h) of this section, the third party payer must reimburse Medicare even though it has already reimbursed the beneficiary or other party.
>
> (2) The provisions of paragraph (i)(1) of this section also apply if a third party payer makes its payment to an entity other than Medicare when it is, or should be, aware that Medicare has made a conditional primary payment.

42 C.F.R. § 411.24(i). In Counts I and II, the United States claims it is entitled to remedy under the double payment regulation because the RSP Defendants are third-party payers who are "required or responsible" to reimburse HCFA under a primary plan of self-insurance. Complaint, ¶¶ 30, 43-44; United States' October 20, 2000, Response, pp. 36-37 (Doc. 41). The RSP Defendants argue the government's claims in Counts I and II must be dismissed because: (1) the double payment remedy is only available against insurers; (2) the double payment remedy is only available when an insurer makes a payment to a Medicare beneficiary with knowledge that the beneficiary owes money to the government; and (3) the double payment remedy is available only when the government has first tried and failed to recover from the beneficiary who received the payment.

1. Are the RSP Defendants MSP Insurers?

The courts have uniformly recognized that the MSP statute's clear purpose was to grant the government a right to recover Medicare costs from insurance entities. *United States v. Philip Morris, Inc.*, 116 F.Supp.2d 131, 146 n. 22 (D.D.C.2000) (collecting cases); *Dow Corning Corp.*, 250 B.R. at 337 n. 22 (unless alleged tortfeasor qualifies as a primary plan or received payment from a primary plan,

MSP does not grant right to initiate direct action against it). The express wording of the statute creates a cause of action against insurers and their payees. *See United States v. Rhode Island Insurers' Insolvency Fund*, 80 F.3d 616, 622 n. 5 (1st Cir.1996) (the MSP provision limits reimbursement to recoveries from "primary plans," whose definition lists only entities that are clearly "within" the insurance industry).

The United States argues it can reach the RSP Defendants even though they are not insurance companies because they are self-insured,[9] in whole or in part, "against the risk of products liability claims by breast implant recipients." Complaint ¶¶ 43-44.[10]

The United States' claim that the RSP Defendants are "self-insured" was initially based on a theory that the RSP settlement was the "plan" of self-insurance. It has now abandoned that claim[11] and relies solely on the argument

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[9] A self insured plan can include the plan of an "entity engaged in a business, trade, or profession ...." 42 C.F.R. § 411.50(b).

[10] The RSP Defendants vigorously dispute the allegation that they are self-insured, and argue that the United States is fully cognizant of the RSP Defendants' insured status. The United States correctly argues that the court must take as true its allegation that the RSP Defendants are self-insured on this motion to dismiss under Fed.R.Civ.P. 12(b)(6). The court notes that the United States' allegation that the RSP Defendants are self-insured or self-insured in part must "to the best of the [signer's] knowledge and belief, formed after an inquiry reasonable under the circumstances ... have evidentiary support, or if specifically so identified, [be] likely to have evidentiary support after a reasonable opportunity for further investigation or study." Fed.R.Civ.P. 11(b).

[11] On October 20, 2000, the government filed a "Notice of Correction" in which it requested deletion of its contention that the RSP and other opt-out settlements were primary plans. (Doc. 41). Accordingly, this court need not determine whether the RSP Settlement is a "primary plan" of self-insurance. The court notes, however, that the settlement does not provide for reimbursement of medical expenses. Rather, it provides specific compensation upon proof of certain symptoms or conditions without regard to actual medical expenses incurred by the claimants. The defendants did not concede liability for the plaintiffs'

that the RSP Defendants themselves are a self-insured "plan" in that they pay a policy deductible or have made payments out of retained earnings. Complaint ¶ 43. This court does not agree that these payments, without more, constitute a "plan" of self-insurance. *See In re Orthopedic Bone Screw Prod. Liab. Litig.*, 202 F.R.D. 154 (E.D.Pa.2001) (Memorandum and Pretrial Order No. 2000); *In re Diet Drugs Prods. Liab. Litig.*, No. MDL 1203, CV 99-20593, 2001 WL 283163 at *9-11 (E.D.Pa. March 21, 2001) (Bechtle, J.).

A self-insured plan is defined by regulation as a "plan under which ... a[n[entity carries its own risk instead of taking out insurance with a carrier." 42 C.F.R. § 411.50(b). A "plan" is "any arrangement, oral or written, by one or more entities, to provide health benefits or medical care or assume legal liability for injury or illness." 42 C.F.R. § 411.21. Therefore, the regulatory language defining "self-insured plan" connotes some type of formal arrangement by which funds are set aside and accessed to cover future liabilities. *See In re Diet Drugs*, 2001 WL 283163 at *10; *Dow Corning*, 250 B.R. at 339. Furthermore, the HCFA itself has stated that "the mere absence of insurance purchased from a carrier does not necessarily constitute a 'plan' of selfinsurance." 54 Fed. Reg. 41727 (Oct. 11, 1989). *See generally Thompson v. Goetzmann*, 2001 WL 771012 at *2 (N.D.Tex.2001) (Lynn, J.) Accordingly, payments of deductibles or payments out of retained earnings, without more, do not constitute a "plan" of self-insurance. [12]

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medical conditions in the settlement, and the United States has not claimed there was any other evidence that the claimants' medical conditions and related medical expenses were caused by breast implants.

[12] The government argues that deductibles and payments out of general assets can be plans of self-insurance because an entity need not carry its "entire" risk, only its "own" risk under § 411.50(b). However, that argument ignores the portion of the same regulatory definition requiring that the self-insurance must be "instead of" taking out insurance with a carrier. 42 C.F.R. § 411.50(b). The government also

Moreover, having abandoned its claim that the RSP settlement fund is a primary plan of self-insurance, the United States continues to claim that the RSP settlement and other opt-out settlements "establish that the RSP Defendants are required or responsible to reimburse HCFA for its conditional payments." United States Response, p. 36 (Doc. 41). This court agrees with the RSP Defendants, in that "[i]f the obligation to pay arises from the RSP and opt-out settlements, as is alleged in the Complaint, and if neither the RSP nor the opt-out settlements are primary plans—as the government now concedes—then the RSP Defendants cannot be third party payers because their obligation to pay does not arise 'under a primary plan.'" 42 U.S.C. § 1395y(b)(2)(B)(ii). RSP Response of October 31, 2000. (Doc. 43).

2. The Third Party Payer's Knowledge.

The RSP Defendants argue the double payment remedy is only available to the United States when an insurer makes a payment to a Medicare beneficiary with knowledge that the beneficiary owes an obligation to reimburse the government for medical services that were paid by the United States.[13] Accordingly, they argue Counts I and II

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argues that the definition of "liability insurance payment" in § 411.50(b) amounts to a regulatory recognition that business entities are routinely self-insured for part of a risk, because it provides that the insurer's payment and the insured's deductible are equally considered to be "liability insurance payments." However, this court is not satisfied that the specific inclusion of deductibles within the definition of "liability insurance payments" amounts to an implied inclusion of deductibles within the definition of "self-insured plan." In fact, it would seem that the specific inclusion in one place supports an argument for a specific exclusion in the other. Finally, as stated in the main text, the government's arguments ignore the requirement that self-insurance be pursuant to a "plan" to provide health benefits or medical care or assume legal liability for injury or illness.

[13] According to the terms of the RSP settlement, the defendants are not privy to the information about the claimants' identities. The court appointed a special master to serve as claims administrator, and the

must be dismissed because the United States has not averred the RSP Defendants made payments to Medicare beneficiaries who they knew to be such beneficiaries. The United States denies that it is required either to plead or to prove that the RSP Defendants acted with knowledge. It claims the RSP Defendants are liable for a second payment to the United States because they were required by law to have ascertained whether any claimant was a Medicare beneficiary and to have ensured that payment was made to the United States before payment was made to a claimant. Complaint, ¶¶ 41, 70. The RSP Defendants counter that they have no duty to investigate any claimant's Medicare history.[14]

In *HIAA v. Shalala*, 23 F.3d 412 (D.C.Cir.1994), the D.C. Circuit considered challenges by health insurers to various regulations HCFA promulgated to implement the MSP statute. The court found one HCFA regulation invalid because it purported to permit a direct right of action against third-party payers who were not contractually "required or responsible" to pay under a primary plan. *HIAA*, 23 F.3d at 419-420 (applying language in 42 U.S.C. § 1395y(b)(2)(B)(ii) (the direct right of action)). Third party payers who make payments according to contractual provisions are no longer "required or responsible to pay" under that contract and not subject to suit under (b)(2)(B)(ii). Therefore, once the third party payer satisfies its contractual obligations, the United States may not claim

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claims administrator receives the information necessary to determine who is entitled to settlement payments. Order 27, RSP ¶¶ H–J. If the defendants knew the identities of the claimants, they still would not have the necessary information to conclude which claimants are Medicare beneficiaries. That information is in the hands of HCFA.

[14] The Escrow Agent characterizes the task of identifying women who might have received federal funds for medical treatment as "herculean." Escrow Agent Submission of June 14, 2000, Doc. 31, p. 11.

a second payment unless it can meet the requirements of the double payment regulation.

The *HIAA* court upheld the double payment regulation based on language limiting HCFA's recovery of a second payment to those situations when the third party payer "is, or should be aware" of Medicare's conditional payment. The court observed the regulation was within the United States' subrogation rights under § 1395y(b)(2)(B)(iii), since a "common feature" of subrogation law is the general principal that an insurer may recover a second time from a tortfeasor who makes payment to the wrong party with knowledge of the insurance company's payment. *See* 16 Couch on Insurance 3d, §§ 224:113, 224:117, 224:121 (3d ed. 2000). Accordingly, the government must proceed as a subrogee against third party payers who have already paid according to the contract, and are no longer "required or responsible" to pay. As subrogee, the government is limited to proceeding against third-party payers who have made their payment with knowledge of the United States' claim.[15]

The United States contends *HIAA* does not apply because the court considered only part of the double payment regulation, § 411.24(i)(2), and that subsection applies only to employee group health plans paying routine, undisputed claims. It argues that under § 411.24(i)(1) it may collect a second payment from liability insurance companies regardless of the insurers' knowledge. However, the *HIAA* court clearly considered the entire double payment regulation without limiting its holding to a specific subsection or to undisputed payments by employee group health plans. Moreover, the *HIAA* court upheld the entire regulation based on its conclusion that the regulation was an expression of the United States' subrogation rights. The construction of the regulation advanced by the United

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[15] Accordingly, the United States must also name its insured to bring an action under the double payment regulation. *See* Part III(A) *supra*.

States here, although plausibly within the wording of the regulation, would render the regulation in excess of the government's subrogation rights under the MSP statute. Congress authorized recovery only from an entity that has already satisfied its obligations under a primary plan to the extent such recovery is authorized by the common law subrogation rights adopted in 42 U.S.C. § 1395y (b)(2)(B)(iii). *HIAA*, 23 F.3d at 417-18, 421-22.

Accordingly, the United States cannot bring a direct action under § 1395y(b)(2)(B)(ii) against an entity that has already satisfied its contractual obligations to the beneficiary. Against such entities, the United States must bring a subrogation action as implemented by the double payment regulation, and must plead and prove the third party payer knew or should have known of Medicare's conditional payments at the time payment was made to the beneficiary.

The United States further argues the RSP Defendants' knowledge of the MSP statute and of the United States' claim that it made conditional payments to unknown breast implant claimants was sufficient to trigger a duty on the part of the defendants to investigate. It also contends the RSP Defendants structured the settlement in a manner so as to avoid obtaining knowledge.[16] However, the government has not cited any authority to support its argument that the RSP Defendants were responsible for

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16 As discussed above, this class action settlement was not, and could not have been, the unilateral product of the RSP Defendants. To the extent the United States has raised a question of fact about the RSP Defendants' intent, it has not established the RSP Defendants were obliged to assume the burden of gathering information about Medicare beneficiaries for HCFA. If the RSP Defendants had obtained knowledge of the claimants' identities, simply knowing the names of the claimants and their medical condition would not have been the "information necessary to draw the conclusion that Medicare ... made a conditional primary payment," since the RSP Defendants still would not have known which claimants were Medicare beneficiaries. *HIAA*, 23 F.3d at 418.

collecting the information needed to help the United States recover its conditional payments. The HCFA is the only entity charged with a duty to identify secondary payer situations under the MSP statute. *See* 42 U.S.C.§ 1395y(b)(5) (requiring HCFA to collect and disseminate information about Medicare beneficiaries, including, *inter alia*, sending questionnaires to individuals applying for benefits "to obtain information on whether the individual is covered under a primary plan ..."). Although the regulations require a third party payer to give notice when it "learns" HCFA has made a payment for which the third party payer was responsible, 42 C.F.R. § 411.25(a), the HCFA considers the regulation "to embrace a situation where a third-party payer 'receives the information necessary to draw the conclusion that Medicare has made a conditional payment ....'" *HIAA*, 23 F.3d at 422. The "should be ... aware" language in the double payment regulation means the third party payer must, at the time of the payment to the wrong party, possess "direct information" of Medicare's conditional payment, or have "information necessary to draw the conclusion that Medicare ... made a conditional primary payment." *HIAA*, 23 F.3d at 418 (quoting from declaration of HCFA representative Olenick). The knowledge that the large group of Medicare beneficiaries and the large group of RSP claimants overlapped to some degree was not sufficient to give the RSP Defendants notice of any specific Medicare payments. Nothing in the statute or regulations supports the United States' claim that the third party payer is required to undertake an investigation for the benefit of the government to discover Medicare's involvement.[17]

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[17] HCFA submitted a brief and a declaration to the *HIAA* court which the RSP Defendants have provided to this court. HCFA's Paul Olenick told the *HIAA* court:

The United States also argues that the extent of the RSP Defendants' actual knowledge is a factual question that cannot be decided on a motion to dismiss. The plaintiff has, however, affirmatively claimed that the RSP Defendants "did not ascertain" whether any claimant had Medicare benefits, and the government acknowledges the RSP Defendants did not have access to this information due to the confidentiality provisions in the RSP settlement. A motion to dismiss is proper where the plaintiff has pled facts defeating its claim. *Clark v. Amoco Prod. Co.*, 794 F.2d 967, 970 (5th Cir.1986) ("a claim may also be dismissed if a successful affirmative defense appears clearly on the face of the pleadings").

3. Reimbursement From Medicare Beneficiaries.

The RSP Defendants claim that the United States must plead and prove that it has sought recovery from its Medicare beneficiaries before proceeding against third party

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> Since the regulation applies only when the third party payer already *has* the knowledge that the regulation requires it to report, compliance does not require third party payers to develop procedures for investigating possible Medicare involvement.

RSP Ex. C, Olenick Decl. ¶ 21 (emphasis in original). In its brief submitted to the *HIAA* court, the United States represented that the recovery under the double payment regulation "would only be possible if, at the time the third party makes its own payment it 'is, or should be, aware' that Medicare has made a conditional payment," and that HCFA construed this standard to mean the third party payer "actually has in its possession information that directly establishes that Medicare has made such a payment." RSP Exhibit G, Brief for the Appellees at 41. The government contends this court cannot consider these documents in deciding this motion to dismiss, *but see Bryant v. Avado Brands, Inc.*, 187 F.3d 1271, 1276 (11th Cir.1999) (approving practice of judicially noticing publicly filed documents with SEC on a motion to dismiss). The court has, however, found consideration of these materials is not necessary in light of its conclusion that the double payment regulation must be applied consistently with general subrogation principles and the discussion of the government's position in *HIAA*.

payers under the double payment regulation. *See* 42 C.F.R. § 411.24(i) (requiring third party payer to make a second payment to Medicare "if Medicare is not reimbursed" by the beneficiary")[18]; 54 Fed. Reg. 41716, 41719 (Oct. 11, 1989) (HCFA has a right to recover its payment from an entity that has already reimbursed the beneficiary if HCFA is unable to recover conditional Medicare payments from the beneficiary); *Faulty Information System Costs Millions in Medicare Payments: Hearings Before the Subcomm. on Regulation and Government Information of the Comm. on Governmental Affairs, United States Senate*, 103d Cong. 1st Sess. 37 (1993) (prepared statement of Carol J. Walton on behalf of HCFA) (an insurer "may rebut the demand for repayment" by demonstrating "that it has ... made a primary payment on the claim, in which case Medicare will pursue collection against the entity that received two... payments.") (RSP Exhibit H).[19] The legislative

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[18] The United States argues it has multiple ways to recover its conditional payments, and there is no specific order of recovery. However, the language in the text is from § 411.24(i) specifically, which is the only regulation permitting the government to recover from third party payers who have already made a payment. The other regulations cited by the government are simply irrelevant to the issue here.

[19] Again, the RSP Defendants cite to the *HIAA* brief and Olenick declaration, in which HCFA represented that it would first try to recover against a beneficiary before attempting to recover a second payment from an insurer. As noted above, the United States argues these materials are extrinsic to the complaint and should not be considered in this motion. The court has found consideration of these materials is not necessary in light of its conclusion that the MSP statutes and regulations require HCFA to attempt collection from its Medicare beneficiaries prior to bringing suit against the insurer. Accordingly, the court has not considered the United States' argument that it cannot be judicially estopped from taking inconsistent positions before this court and the *HIAA* court. *But see Mazza v. Secretary of HHS*, 903 F.2d 953, 959 (3d Cir.1990) (rejecting agency's asserted interpretation of statute and regulations where it "flatly contradict[ed] the position that the agency had enunciated" in prior litigation "closer to the enactment of the governing statute"); *Pfaff v. United States HUD*, 88 F.3d 739, 748 (9th

history supports this conclusion, noting that the "bill establishes the statutory right of Medicare to recover directly from a liable third party, if the beneficiary himself does not do so." H.R.Rep. No. 98-432 Part II, at 1803 (1984), U.S.Code Cong. & Admin.News 1984, pp. 697, 1417.[20]

The United States argues it has made attempts to recover from beneficiaries. *See* Declaration of Barbara Wright in support of motion for preliminary injunction at ¶¶ 10-12, 17-20, 27. Nothing in the complaint or the materials subject to judicial notice supports the RSP Defendants' assertion that the United States has made no effort to recover from Medicare beneficiaries. Accordingly, this issue cannot be resolved on a motion to dismiss.

B. Count II—The Claim For Double Damages.

In addition to its claim for a double payment from the RSP Defendants, the United States claims it is entitled to double damages pursuant to 42 C.F.R. § 411.24(c)(2), which provides:

> If it is necessary for HCFA to take legal action to recover from the primary payer, HCFA may recover twice the amount [of the Medicare primary payment].

Id. However, double damages are available to the United States only when an entity that is required or responsible to

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Cir.1996) (rejecting new interpretation of statute where department's "inconsistent and misleading representations" had "led [those regulated by the statute] down the garden path").

[20] The United States argues that the statutory and regulatory scheme specifically contemplates HCFA will proceed against the third party prior to proceeding against the beneficiary in some cases. The court agrees that HCFA may proceed with a direct action against a third party payer who has not yet made any payment to the beneficiary or the provider. 42 U.S.C. § 1395y(b)(2)(B)(ii); 42 C.F.R. § 411.23. However, the United States has not pointed to any provision of the regulations that permits it to collect a second payment from a third party without first attempting to collect from the beneficiary.

pay under a primary plan "fails to provide for primary payment." 42 U.S.C. §§ 1395y(b)(2)(B)(ii), (b)(3)(A); *United States v. Sosnowski*, 822 F.Supp. 570, 573 (W.D.Wis.1993). As discussed above, there is considerable doubt whether the RSP Defendants paid under a primary plan.

The RSP Defendants also argue that, if they were a primary plan, they have satisfied any contractual obligation to make their payment. The United States' claim to double damages must be brought "in accordance with [the provision for a private cause of action in] paragraph (3)(A) ...." *See* 42 U.S.C. §§ 1395y(b)(2)(B)(ii); (b)(3)(A). Paragraph (b)(3)(A) permits double damages when "a primary plan ... fails to provide for primary payment (or appropriate reimbursement) ...." *Id.* The RSP Defendants claim they have made their "primary payment" to the breast implant claimants. The United States argues, without citation, that the primary payment must be made to the medical care provider. It further argues that it may seek double damages when the primary payer fails to make "appropriate reimbursement" to Medicare.

The primary payer must either make a primary payment or reimburse Medicare's conditional payment to avoid double damages. 42 U.S.C. § 1395y(b)(3)(A). It is undisputed that the RSP Defendants have made payments to breast implant claimants. There is no statutory or regulatory support for the United States' argument that payment must be made to the medical care provider to avoid double damages. Neither is there any support for the United States' argument that reimbursement must be made in addition to payment to avoid double damages. In explaining § 411.24(c), HCFA said "any claimant may seek double damages from any entity responsible for payment that fails to pay primary benefits as required by the statute." 60 Fed. Reg. 45344, 45345 (Aug. 31, 1995).

The claim of the United States for double damages in Count II of the complaint is due to be dismissed.

C. Count V—The Claim for Declaratory Relief under the MSP.

In Count V, the United States requests a declaration that "the RSP Defendants are liable to reimburse HCFA for past payments made to breast implant claimants, whether through the RSP, as opt-out settlement payments, or non-MDL payments ... that the RSP Defendants must give the HCFA notice of all payments to Medicare beneficiaries ... and ... that all defendants must ensure before payment is made to any Claimant that appropriate payment is made to the United States."

To the extent the United States is seeking a declaration with regard to past payments made to RSP claimants, the claim is foreclosed for the same reasons the other MSP claims are foreclosed. The United States also claims it is entitled under 42 C.F.R. § 411.25 to a declaration that the RSP Defendants must give notice of all future payments to Medicare beneficiaries and "ensure" that the United States is paid first. However, 42 C.F.R. § 411.25 only applies to a "third party payer" who "learns" Medicare has made a specific payment for a given item or service. *See* 59 Fed. Reg. 4285, 4286 (Jan. 31, 1994). At the most, the regulation requires the third party payer to give notice when it "is, or should be, aware" of Medicare's primary payment, but it does not, by its express terms, require any type of private monitoring. *See HIAA*, 23 F.3d at 421-22. Neither the MSP nor the regulation impose a duty on the RSP Defendants to investigate, or "ensure" that payment is made to the United States before payment is made to any Claimant. Accordingly, Count V is due to be dismissed.

V. COUNTS III, VI, AND VII—THE CLAIMS AGAINST THE RSP DEFENDANTS AND THE ESCROW AGENT AS ENTITIES THAT RECEIVED PAYMENT.

In Count III, the United States claims that the RSP Defendants are required to reimburse HCFA as entities that "received payment," even if they are not third party payers. Compl. ¶¶ 63-65. In Count VI, the United States claims the Escrow Agent is liable to reimburse the government as an entity that received payment. Compl. ¶¶ 71-74. In Count VII, the United States requests an order enjoining the Escrow Agent from continuing to make payments to RSP claimants pending inquiry into the Medicare eligibility of claimants, to stop disbursements of payments to claimants who are found to have been eligible for Medicare benefits, to disclose the identities and information concerning all payments made or contemplated to be made to Medicare beneficiaries, and to implement procedures to ensure that the United States' claims under the MSP statute are provided for prior to disbursement of further funds from the MDL Settlement Fund. In its submission of July 14, 2000, the United States expressly disavowed any claim to damages from the Escrow Agent. *Id.* at 25.

The defendants contend the United States' claims against them as entities that "received payment" must be dismissed because (1) there is no allegation they knew or should have known of any conditional payments by Medicare to any claimant;[21] (2) an entity that merely processes payments is not subject to liability under the MSP

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[21] As discussed in Part IV(2), the HCFA finds this condition met only when a "third party payer 'has in its possession direct information that Medicare has made a conditional primary payment.'" *HIAA*, 23 F.3d at 418 (quoting Declaration of Paul Olenick). The United States has not shown that the MSP statute imposes a duty to investigate and discover Medicare conditional payments.

statute;[22] and (3) the United States does not have a claim against property under the MSP statute.[23]

Paragraph (2)(B)(ii) names only two entities subject to suit by the United States; entities that are "required or responsible" to pay and entities that "received payment." The United States has previously unsuccessfully argued that intermediaries that receive and pass on funds are "required or responsible" to pay. *See HIAA*, 23 F.3d at 415-17; *United States v. Travelers Ins. Co.*, 815 F.Supp. 521, 523-24 (D.Conn.1992); *Provident Life and Accident Ins. Co. v. United States*, 740 F.Supp. 492, 503-04 (E.D.Tenn.1990); *United States v. Blue Cross and Blue Shield of Michigan*, 726 F.Supp. 1517, 1521-22 (E.D.Mich.1989). These courts concluded that Congress did not intend to make these entities subject to recovery action.[24] This court agrees that such entities, even to the extent they "received payment" as

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[22] The United States avers that the Escrow Agent "received payments from the RSP Defendants and/or their insurers in order to pay breast implant claims." (Compl. ¶ 47). The United States avers that the "RSP Defendants received payments from products liability insurers or caused such payments to be made in order to compensate Claimants for their alleged breast implant-related injuries." Complaint, ¶ 64. Thus, it claims the defendants received and passed on the funds Medicare is claiming, not that the defendants have possession of the funds.

[23] As discussed in Part III, *supra*, the United States must also identify its Medicare beneficiaries and the items or services it provided to proceed under the MSP with either a direct action or a subrogation action under 42 U.S.C. § 1395y(b)(2)(B).

[24] The third party administrators and banks discussed in *HIAA v. Shalala*, 23 F.3d 412, 415-17 (D.C.Cir.1994), assumed no personal financial responsibility for paying the plan's benefits. "In the context of the MSP scheme ... it would be wholly unreasonable for HCFA to treat the bank as a responsible payer subject to recovery actions." *Id.* at 416. "[T]he existence of contracts under which the financial liability is 'murky' seems an odd justification for imposing it on a party to—by perfectly clear contract—is plainly not liable." *Id.*

is now argued by the United States, are not liable for Medicare conditional payments. [25]

Courts must give the words in a statute their contemporary, common meaning absent an indication Congress intended them to bear some different import. *Williams v. Taylor*, 529 U.S. 420, 431-2, 120 S.Ct. 1479, 146 L.Ed. 2d 435 (2000). In ordinary usage, the term "receive" connotes an attendant degree of possession. Webster's New International Dictionary, 1894 (3d ed.1976) (defining "receive," *inter alia*, as "to take possession or delivery of"). "Payment" is the "performance of an obligation" or the "money or other valuable thing so delivered in satisfaction of an obligation." Black's Law Dictionary, 1150 (7th ed. 1999). Intermediaries who facilitate the transfer of a payment only receive temporary possession of funds intended for payment; they do not receive permanent possession of funds in satisfaction of an obligation. Only the ultimate payee receives funds in satisfaction of an obligation. Thus, the very language relied upon by the United States does not support its claim. Although intermediaries technically "receive" funds in the course of making transfers between the payer and payee, they do not in any sense receive a "payment."

The United States' allegations establish that the RSP Defendants and the Escrow Agent, if they are liable under the MSP at all, are liable as payers and not payees. Nothing

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[25] No party has offered any useful legislative history or administrative interpretation with respect to this section of the statute. Other than its reliance on the "received payment" language from paragraph (2)(B)(ii), the United States has not pointed to any support in the statute or regulations for its claim that entities who merely receive and pass on insurance monies to pay settlement claims are "entities that receive payment" within the meaning of the statute. The litigation position of agency counsel that is wholly unsupported by regulations, rulings, or administrative practice is not entitled to deference. *Bowen v. Georgetown University Hosp.*, 488 U.S. 204, 211, 109 S.Ct. 468, 102 L.Ed.2d 493 (1988).

in the language or general intent of the statute indicates Congress intended an entity that received interim possession of funds in the process of making payment to be liable as an entity that "received payment." Common sense dictates that such entities are aligned with the entity "required or responsible" to pay and not with the payee.[26]

Furthermore, reading the "received payment" clause in conjunction with the remaining portions of paragraph (2)(B)(ii) supports the view that Congress intended to permit recovery from only those entities who were ultimately responsible to make payment or who ultimately received payment, and not from intermediaries to the transaction. First, the stated intent of paragraph (2)(B)(ii) is to permit the government to "recover payment." *Id.* The most straightforward way to "recover" payment is to proceed against those entities most likely to have possession of the funds that should have been used to reimburse Medicare's conditional payment. The government does not have a reasonable claim that it is "recovering" payment from an entity that is not holding the funds intended for the payment. There is no language that can be construed to support the United States' claim that Congress intended to impose liability for Medicare's conditional payments on an innocent entity that merely received and passed on funds. Such strict liability is extraordinary, and the argument that Congress imposed this kind of liability *sub silentio* is absurd.

Second, under paragraph (2)(B)(ii) the payer can be sued only when it is "required or responsible" to pay, so that once it makes payment and is no longer "required or responsible" it cannot be reached under the statute. In view of this specific treatment of payers, it is most unlikely that Congress intended to create greater liability for

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26 The Escrow Agent is more correctly characterized as a neutral intermediary, who owes a duty to all the parties to the transaction. *See* 28 AmJur 2d, Escrow § 20 (2000).

intermediaries who merely receive and pass on payment on behalf of the payer.

Third, paragraph (2)(B)(ii) specifically names two examples of entities that received payment, physicians and providers. Physicians and providers are typically final receivers of the third party payment, not pass-through payees. The specific listing of entities who are likely to be in final possession of the funds and the exclusion of entities who merely receive and pass on possession indicate pass-through payers who are not subject to suit as entities that received payment.

Finally, the only parties named in paragraph (2)(B)(ii) that typically function as pass-through payers, third party administrators, are liable only if they have access to the funds claimed for Medicare reimbursement. It is unlikely that Congress intended to impose a greater liability on similarly situated entities through more general language in the statute. *And see HIAA*, 23 F.3d at 415-417 (prior to amendment imposing limited liability on third party administrators, finding third party administrators are not properly subject to liability under the MSP even though they are literally "required or responsible" to pay).[27]

Moreover, nothing in the HCFA's own regulations supports the argument presently offered by the government. If the agency has ever previously interpreted paragraph (2)(B)(ii) to permit the extraordinary liability it

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[27] Subsequent to the *HIAA* decision, paragraph (2)(B)(ii) was amended to permit recovery from third party administrators, provided the third party administrator is able to recover from the "employer or group health plan" or is employed by the "employer or group health plan" and is not providing administrative services due to bankruptcy or insolvency. 1997 Amendments, Pub. L. No. 105-33, § 4633(a); 42 U.S.C. § 1395y(b)(2)(B)(ii). As discussed in the text, the amendment supports this court's interpretation of paragraph (2)(B)(ii), since it permits recovery only from third party administrators who have access to the funds the government is trying to recover.

argues here, it has not said so. The HCFA regulation providing for recovery from parties that receive third party payments provides the United States "has a right of action to recover its payments from any entity, including a beneficiary, provider, supplier, physician, attorney, State agency or private insurer that has received a third party payment." 42 C.F.R. § 411.24(g). The entities listed in § 411.24(g) are typical "final recipients" of third party payments. The list's inclusion of ultimate payees and exclusion of pass-through payers indicates HCFA recognizes it is permitted recovery from entities that ultimately received payment, not from entities who no longer hold funds to which HCFA has a claim. An entity that has received payment *and* "already reimbursed the beneficiary or other party" must be pursued under HCFA's "special rules" that are applicable only when third party payers have knowledge or imputed knowledge. 42 C.F.R. §§ 411.24(h), 411.24(i).[28]

Accordingly, this court finds the only entities that may be sued by the United States pursuant to paragraph (2)(B)(ii) are those entities who are ultimately responsible to pay or who ultimately receive payment. This conclusion is supported by reading paragraph (2)(B)(ii) as a whole rather than focusing on the language in a single clause, and by adhering to the stated and implied intent of Congress that the statute was designed to effectuate. Nothing in the MSP statute or the HCFA's regulations supports this action against entities who have received and passed on payment.

The United States also argues HCFA will be severely hamstrung in effectuating Congress's goal of making

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[28] Subsection 411.24(h) provides, "[i]f the beneficiary or other party receives a third party payment, the beneficiary or other party must reimburse Medicare within 60 days." Subsection 411.24(i) provides that "if Medicare is not reimbursed as required by paragraph (h) ... the third party payer must reimburse Medicare even though it has already reimbursed the beneficiary or other party."

Medicare a secondary payer if this court analogizes the Escrow Agent to a third party administrator, since the Escrow Agent is the only party with knowledge of the claimant's identities. However, the Escrow Agent is not the intended target of the MSP, and proceeding against the Escrow Agent will not effectuate Congress's intent.

The United States specifically avers that the RSP Defendants and the Escrow Agent receive and pass on funds to claimants. The orders in MDL 926 further establish that the Escrow Agent is required to hold and administer the RSP funds, and to disburse the funds in accord with the terms of the orders entered in MDL 926, but he is not ultimately liable for payment and he does not ultimately receive payment. *See, e.g. In re Silicone Gel Breast Implant Products Liability Litigation* (MDL 926), No. CV 92-N-10000-S, Orders of November 4, 1993; April 11, 1994; November 23, 1994; March 25, 1996; May 31, 1996; July 15, 1996; September 25, 1999. The United States has not alleged facts that, if proved, would entitle it to recover from the RSP Defendants or the Escrow Agent as entities that "received payment."[29] Accordingly, Counts III, VI, and VII are due to be dismissed.

VI. COUNTS VIII AND IX—THE MCRA CLAIMS.

In Count VIII, the United States claims it is entitled to equitable relief under the Medical Care Recovery Act ("MCRA"), 42 U.S.C. § 2651 *et seq.*, requiring the Escrow

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[29] The United States denies it is bringing this action against the Common Benefit Fund or the MDL 926 Settlement Fund and relies solely on its claims against the Escrow Agent as an entity that "received payment." It points out that its ultimate objective of recovering money does not convert its claim into an action against property. *See e.g., Cox v. Shalala*, 112 F.3d 151, 154-55 (4th Cir.1997) (permitting recovery from a settlement fund where funds are in an escrow account); *Waters v. Farmers Texas County Mut. Ins. Co.*, 9 F.3d 397 (5th Cir.1993) same); *Zinman v. Shalala*, 835 F.Supp. 1163, 1171 (N.D.Cal.1993), *aff'd* 67 F.3d 841 (9th Cir.1995).

Agent to implement procedures to identify United States' beneficiaries who are eligible for RSP and Common Benefit Fund payments, and enjoining the Escrow Agent from making further payments to claimants pending inquiry into the eligibility of claimants to medical care provided or paid by the United States. In Count IX, the United States demands payment from the MDL 926 Settlement Fund of its reasonable costs of providing medical care to RSP claimants.

The MCRA provides, in pertinent part:

> In any case in which the United States is authorized or required by law to furnish or pay for hospital, medical, surgical or dental care or treatment ... under circumstances creating a tort liability upon some third person ... to pay damages therefor, the United States shall have a right to recover (independent of the rights of the injured or diseased person) from said third person, or that person's insurer, the reasonable value of the care and treatment so furnished, to be furnished, paid for, or to be paid for and shall, as to this right be subrogated to any right or claim that the injured or diseased person ... has against such third person ....

42 U.S.C. § 2651(a).

> The United States may, to enforce a right under subsections (a), (b), and (c) of this section ... (2) institute and prosecute legal proceedings against the third person who is liable for the injury or disease or the insurance carrier or other entity responsible for the payment or reimbursement of medical expenses or lost pay ..."

42 U.S.C. § 2651(d).[30]

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[30] Prior to 1996 MCRA amendments, the MCRA provided for recovery from the tortfeasor only. The 1996 Amendments provided for recovery from the tortfeasor or the tortfeasor's insurer and included the right to bring action against the "insurance carrier or other entity responsible for

The defendants argue MCRA claims must be brought against a tortfeasor or the insurance company of a tortfeasor. The MCRA does not permit the United States to pursue its claims against a settlement fund.[31] *Holbrook v. Andersen Corp.*, 996 F.2d 1339, 1341-42 (1st Cir.1993); *United States v. Farm Bureau Ins. Co.*, 527 F.2d 564, 566 (8th Cir.1976); *In re Orthopedic Bone Screw Prod. Liab. Litig.*, 176 F.R.D. 158, 179 (E.D.Pa.1997); *United States v. Cipinko*, 1994 U.S. Dist. LEXIS 15084, 1994 WL 589455, *1 (N.D.Cal.1994); *GEIC v. Andujar*, 773 F.Supp. 282, 286 (D.Kan.1991); *United States v. Jackson*, 572 F.Supp. 181, 184-85 (W.D.Mich.1983).

Pointing to 42 U.S.C. § 2651(d), the United States argues the 1996 Amendments to the MCRA permit it to sue the "insurer or other entity responsible for the payment or reimbursement" of medical expenses. However, a complete reading of § 2651 refutes the United States' claim. A subsection (d) enforcement action may be brought only to enforce the United States rights under subsections (a), (b) and (c). 42 U.S.C. § 2651(d). Subsection (a) specifically limits the United States' right of recovery to "said third person [tortfeasor], or that person's insurer." 42 U.S.C. § 2651(a). Subsections (b) and (c) do not broaden the United States' rights to permit recovery from a settlement fund. Although the 1996 Amendments expanded the MCRA to reach the insurer of a tortfeasor, there is no indication in the

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the payment or reimbursement of medical expenses or lost pay." Pub. L. 104-201, § 1075(b)(1) and (2) (1996).

[31] The United States points to the settlement agreement, arguing that the injured person cannot affect the Government's MCRA claim by giving a release to the tortfeasor and that it may sue the Escrow Agent because the RSP Defendants "knowingly and voluntarily" transferred responsibility to pay medical expenses to the Escrow Agent. However, the settlement agreement did not affect the United States' rights in any way, neither extinguishing the right to proceed against the RSP Defendants as tortfeasors, nor creating a right to proceed against the Escrow Agent as custodian of the settlement funds.

statutory language that Congress intended to change the limitations established in *Holbrook* related to recovery from a settlement fund. Neither has the United States pointed to any legislative history or court decisions supporting its argument that the 1996 Amendments changed the MCRA to permit recovery from a settlement fund. *See In re Diet Drugs*, 2001 WL 283163, *8 (E.D.Pa. March 21, 2001) (Bechtle, J.).

Moreover, even after the 1996 Amendments, the United States' right to recover remains contingent upon a determination that the government paid for medical care under "circumstances creating a tort liability upon some third party." 42 U.S.C. § 2651(a). There has been no such determination in this case, or in any case involving a settlement of tort claims. *Holbrook*, 996 F.2d at 1341.

Furthermore, the Escrow Agent is not "responsible" under the RSP for "payment or reimbursement of medical expenses." The RSP Settlement fund provides specific compensation upon proof of certain symptoms or conditions without regard to the actual medical costs incurred by the claimants. There is no link between the medical care required or obtained by a particular claimant and the amount of money paid by the fund. *See generally, Lindsey v. Dow Corning Corp.*, No. CV 94-P-11558-S (N.D.Ala.) (Order 27). The Common Benefit Fund provides funds for the payment for services and costs incurred for the common benefit of all silicone gel breast implant claimants, and has no relationship to medical expenses. Furthermore, as discussed above, the Escrow Agent only distributes RSP funds as directed by the court, and thus cannot be said to be "responsible" for the payment of "medical expenses."

The United States alternatively argues that it is a third-party beneficiary of the RSP settlement funds. *See Commercial Union Ins. Co. v. United States*, 999 F.2d 581, 587-88 (D.C.Cir.1993); *Cockerham v. Garvin*, 768 F.2d 784,

787 (6th Cir.1985); *United States v. Nation*, 299 F.Supp. 266, 267 (N.D.Okla.1969). In *Cockerham*, the settlement agreement included a stipulation that the plaintiff would place $20,000 in escrow until he reached a settlement with the government. The *Cockerham* court concluded that the government was a third-party beneficiary of the settlement agreement between the tortfeasor and the injured party. In *Commercial Union*, the tortfeasor's insurer filed an interpleader action and named the United States as one of the competing claimants to the fund in question. The *Commercial Union* court was not concerned with the United States' right to recover from a settlement fund. Similarly, in *Nation*, the parties deposited a disputed portion of settlement funds into the court's registry and the court had only to decide whether the United States would share the disputed funds with the injured party's attorney.

Although it did not allege it was a third-party beneficiary of the RSP, the United States now argues *Cockerham*, *Commercial Union*, and *Nation* are controlling because the RSP Settlement includes a provision which "can be likened to the stipulation creating the escrow agreement" in *Cockerham*. United States' Opposition of July 14, 2000, p. 42 (Doc. 32). The United States relies on paragraph K.4 of the RSP, which provides:

> Subrogation-type claims by insurers or governmental agencies based on payment of medical expenses of participants will, to the extent enforceable under applicable laws, be the responsibility of eligible participants; settling defendants will have no additional responsibilities to such insurers and agencies and will be protected by participants against such claims.

RSP, ¶ K.4. The United States argues it may, through discovery, find the RSP Defendants compensated claimants for medical care expenses in return for the release in ¶ K.4.

However, even such a discovery would be insufficient. Paragraph K.4 is indistinguishable from the provision in the *Holbrook* settlement in which the injured party agreed to indemnify the defendant against the claims of the United States. Unlike the *Cockerham* settlement, there are no explicit RSP terms setting specific funds aside to cover the government's claims. The ¶ K.4 indemnity provision does not establish a fund set aside to satisfy the Government's claim.

The MCRA claims of the United States against the Escrow Agent are due to be dismissed.

VII. THE ESCROW AGENT'S JUDICIAL IMMUNITY.

The MSP and MCRA claims against the Escrow Agent must also be dismissed because he is not subject to liability for the relief claimed by the United States.

The Escrow Agent is a court-appointed intermediary who performs, on behalf of the court, as a disinterested conduit of the settlement funds. *See e.g., In re Silicone Gel Breast Implant Prods. Liab. Litig., MDL 926*, CV-92-N-10000-S; Order 27 and Orders of April 11, 1994; November 4, 1993; November 23, 1994; March 25, 1996; May 31, 1996; July 15, 1996; September 25, 1999; and March 14, 2000. He is not assigned any role in the determination of benefits to be received by RSP claimants. *Id. See* 28 AmJur 2d, Escrow § 20 (2000). In his role as an agent of the court, he has been given immunity for acts he takes in good faith, for all payments to claimants made in the RSP, and for all rebate payments from the Common Benefit Fund. *See MDL 926* Orders of May 31, 1996, ¶ 2 and March 14, 2000, ¶ 3. Judges have absolute immunity from damages for actions taken while they are acting in their judicial capacity, unless they acted in the "clear absence" of all jurisdiction. *Stump v. Sparkman*, 435 U.S. 349, 356-57, 98 S.Ct. 1099, 55 L.Ed.2d 331 (1978); *Simmons v. Conger*, 86 F.3d 1080, 1084-85 (11th

Cir.1996). The United States argues the Escrow Agent is not a judge, and is not therefore entitled to judicial immunity. However, the Escrow Agent was appointed by the court as a special master to carry out limited judicial functions under the direction of the court. In that role, the Escrow Agent is acting in a judicial capacity and enjoys judicial immunity. Accordingly, claims for damages cannot be maintained against the Escrow Agent.

The claims of the United States against the Escrow Agent in which the plaintiff seeks prospective declaratory and injunctive relief under the MSP and the MCRA are not subject to judicial immunity. However, neither the MSP nor the MCRA permits the United States to bring an action for injunctive or declaratory relief to recover medical costs. The MSP permits the United States to "recover payment" as provided in 42 U.S.C. § 1395y(b)(2)(B)(ii), and the MCRA permits the United States to recover the "reasonable value of the care and treatment" as provided in 42 U.S.C. § 2651(a). Both statutes permit recovery for payments made by the government, not prospective declaratory or injunctive relief. Equitable relief is available only where there is no adequate remedy at law. *Mitsubishi Int'l Corp. v. Cardinal Textile Sales, Inc.*, 14 F.3d 1507, 1518 (11th Cir.1994). The court is not obliged to entertain a claim for declaratory judgment where the party has an alternative means of relief. *Angora Enterprises v. Condominium Assn. of Lakeside Village, Inc.*, 796 F.2d 384, 387-88 (11th Cir.1986); *and see Cunningham v. Adams*, 808 F.2d 815, 821 (11th Cir.1987) ("An injury is 'irreparable' only if it cannot be undone through monetary remedies"). The United States has legal remedies available under the MSP and the MCRA, and its claims for equitable and declaratory relief should, therefore, be dismissed.

VIII. CONCLUSION.

A complaint must "show[] that the pleader is entitled to relief," Fed.R.Civ.P. 8(a)(2), and a complaint based upon "conclusory allegations and unwarranted deductions of fact" is subject to dismissal under Rule 12(b)(6). *South Fla. Water Mgt. Dist. v. Montalvo*, 84 F.3d 402, 408 n. 10 (11th Cir.1996). The court may dismiss a complaint pursuant to Fed. R. Civ. P. 12(b)(6) when, on the basis of a dispositive issue of law, no construction of the factual allegations will support the cause of action. *Marshall Cty. Bd. of Ed. v. Marshall Cty. Gas Dist.*, 992 F.2d 1171, 1174 (11th Cir. 1993).

As discussed herein, that is the present case. Thus, this action is due to be dismissed with prejudice. A separate order will be entered.

UNITED STATES DISTRICT COURT FOR THE
NORTHERN DISTRICT OF ALABAMA
SOUTHERN DIVISION.

Master File No. CV-92-N-10000-S,
CV-00-N-0837-S

In re: Silicone Gel Breast Implants Products Liability Litigation (MDL 926)

UNITED STATES OF AMERICA,

v.

BAXTER INTERNATIONAL, INC., ET AL.

[ENTERED Sep 26, 2001].

ORDER

In accord with the Memorandum of Opinion entered contemporaneously herewith, this action is hereby **DISMISSED** with prejudice. Each party shall bear its own costs.

Done, this 26th of September, 2001.

/s/ Edwin Nelson
EDWIN L. NELSON
UNITED STATES CIRCUIT JUDGE

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 01-16782-CC

UNITED STATES OF AMERICA,
Plaintiff-Appellant,
v.
BAXTER INTERNATIONAL, INCORPORATED;
BAXTER HEALTHCARE CORPORATION, et al.,
Defendants-Appellees,

PLAINTIFFS' STEERING COMMITTEE,
Defendant-Intervenor-Appellee

[Filed U.S. Court of Appeals, Eleventh Circuit,
December 23, 2003, Thomas K. Kahn, Clerk]

On Appeal from the United States District Court for the
Northern District of Alabama

BEFORE: TJOFLAT, ANDERSON and CUDAHY*, Circuit Judges

PER CURIAM:

The petition(s) for rehearing filed by Appellee, Plaintiffs' Steering Committee, is DENIED

ENTERED FOR THE COURT:

/s/ R. Lanier Anderson
UNITED STATES CIRCUIT JUDGE

* Honorable Richard D. Cudahy, United States Circuit Judge for the Seventh Circuit, sitting by designation.

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 01-16782-CC

UNITED STATES OF AMERICA,
Plaintiff-Appellant,
v.
BAXTER INTERNATIONAL, INCORPORATED;
BAXTER HEALTHCARE CORPORATION, et al.,
Defendants-Appellees,

PLAINTIFFS' STEERING COMMITTEE,
Defendant-Intervenor-Appellee

[Filed U.S. Court of Appeals, Eleventh Circuit,
December 23, 2003, Thomas K. Kahn, Clerk]

On Appeal from the United States District Court for the
Northern District of Alabama

ON PETITION(S) FOR REHEARING AND PETITION(S) FOR REHEARING EN BANC
(Opinion _____, 11th Cir., 19__, ___ F.2d ____).

BEFORE: TJOFLAT, ANDERSON and CUDAHY*, Circuit Judges

PER CURIAM:

The Petition(s) for Rehearing are DENIED and no Judge in regular active service on the Court having requested that the Court be polled on rehearing en banc (Rule 35, Federal

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* Honorable Richard D. Cudahy, United States Circuit Judge for the Seventh Circuit, sitting by designation.

Rules of Appellate Procedure), the Petition(s) for Rehearing En Banc are DENIED.

ENTERED FOR THE COURT:

/s/ R. Lanier Anderson
UNITED STATES CIRCUIT JUDGE

42 U.S.C. § 1395y
(prior to December 2003 amendments)

§ 1395y. Exclusions from coverage and medicare as secondary payer

* * *

(b) Medicare as secondary payer

(1) Requirements of group health plans

(A) Working aged under group health plans

(i) In general

A group health plan—

(I) may not take into account that an individual (or the individual's spouse) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this subchapter under section 426(a) of this title, and

(II) shall provide that any individual age 65 or older (and the spouse age 65 or older of any individual) who has current employment status with an employer shall be entitled to the same benefits under the plan under the same conditions as any such individual (or spouse) under age 65.

(ii) Exclusion of group health plan of a small employer

Clause (i) shall not apply to a group health plan unless the plan is a plan of, or contributed to by, an employer that has 20 or more employees for each working day in each of 20 or more calendar weeks in the current calendar year or the preceding calendar year.

(iii) Exception for small employers in multiemployer or multiple employer group health plans

Clause (i) also shall not apply with respect to individuals enrolled in a multiemployer or multiple employer group health plan if the coverage of the individuals under the plan is by virtue of current employment status with an employer that does not have 20 or more individuals in current employment status for each working day in each of 20 or more calendar weeks in the current calendar year and the preceding calendar year; except that the exception provided in this clause shall only apply if the plan elects treatment under this clause.

(iv) Exception for individuals with end stage renal disease

Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 426 of this title) would upon application be, entitled to benefits under section 426-1 of this title.

(v) "Group health plan" defined

In this subparagraph, and subparagraph (C), the term "group health plan" has the meaning given such term in section 5000(b)(1) of Title 26, without regard to section 5000(d) of Title 26.

(B) Disabled individuals in large group health plans

(i) In general

A large group health plan (as defined in clause (iii)) may not take into account that an individual (or a member of the individual's family) who is covered under the plan by virtue

of the individual's current employment status with an employer is entitled to benefits under this subchapter under section 426(b) of this title.

(ii) Exception for individuals with end stage renal disease

Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 426 of this title) would upon application be, entitled to benefits under section 426-1 of this title.

(iii) "Large group health plan" defined

In this subparagraph, the term "large group health plan" has the meaning given such term in section 5000(b)(2) of Title 26, without regard to section 5000(d) of Title 26.

(C) Individuals with end stage renal disease

A group health plan (as defined in subparagraph (A)(v))—

(i) may not take into account that an individual is entitled to or eligible for benefits under this subchapter under section 426-1 of this title during the 12-month period which begins with the first month in which the individual becomes entitled to benefits under part A under the provisions of section 426-1 of this title, or, if earlier, the first month in which the individual would have been entitled to benefits under such part under the provisions of section 426-1 of this title if the individual had filed an application for such benefits; and

(ii) may not differentiate in the benefits it provides between individuals having end stage renal disease and other individuals covered by

such plan on the basis of the existence of end stage renal disease, the need for renal dialysis, or in any other manner;

except that clause (ii) shall not prohibit a plan from paying benefits secondary to this subchapter when an individual is entitled to or eligible for benefits under this subchapter under section 426-1 of this title after the end of the 12-month period described in clause (i). Effective for items and services furnished on or after February 1, 1991, and before August 5, 1997, (with respect to periods beginning on or after February 1, 1990), this subparagraph shall be applied by substituting "18-month" for "12-month" each place it appears. Effective for items and services furnished on or after August 5, 1997, (with respect to periods beginning on or after the date that is 18 months prior to such date), clauses (i) and (ii) shall be applied by substituting "30-month" for "12-month" each place it appears.

(D) Treatment of certain members of religious orders

In this subsection, an individual shall not be considered to be employed, or an employee, with respect to the performance of services as a member of a religious order which are considered employment only by virtue of an election made by the religious order under section 3121(r) of Title 26.

(E) General provisions

For purposes of this subsection:

(i) Aggregation rules

(I) All employers treated as a single employer under subsection (a) or (b) of section 52 of Title 26 shall be treated as a single employer.

(II) All employees of the members of an affiliated service group (as defined in section 414(m) of Title 26) shall be treated as employed by a single employer

(III) Leased employees (as defined in section 414(n)(2) of Title 26) shall be treated as employees of the person for whom they perform services to the extent they are so treated under section 414(n) of Title 26.

In applying sections of Title 26 under this clause, the Secretary shall rely upon regulations and decisions of the Secretary of the Treasury respecting such sections.

(ii) Current employment status defined

An individual has "current employment status" with an employer if the individual is an employee, is the employer, or is associated with the employer in a business relationship.

(iii) Treatment of self-employed persons as employers

The term "employer" includes a self-employed person.

(F) Limitation on beneficiary liability

An individual who is entitled to benefits under this title and is furnished an item or service for which such benefits are incorrectly paid is not liable for repayment of such benefits under this paragraph unless payment of such benefits was made to the individual.

(2) Medicare secondary payer

(A) In general

Payment under this subchapter may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that—

(i) payment has been made, or can reasonably be expected to be made, with respect to the item or service as required under paragraph (1), or

(ii) payment has been made or can reasonably be expected to be made under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance.

In this subsection, the term "primary plan" means a group health plan or large group health plan, to the extent that clause (i) applies, and a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance, to the extent that clause (ii) applies

(B) Conditional payment

(i) Repayment required

Any payment under this subchapter with respect to any item or service to which subparagraph (A) applies shall be conditioned on reimbursement to the appropriate Trust Fund established by this subchapter when notice or other information is received that payment for such item or service has been or could be made under such subparagraph. If reimbursement is not made to the appropriate Trust Fund before the expiration of the 60-day period that begins on the date such notice or other information is received, the Secretary may charge interest (beginning with the date on which the notice or other information is received) on the amount of the reimbursement until reimbursement is made (at a rate determined by the Secretary in accordance with regulations of the Secretary of

the Treasury applicable to charges for late payments).

(ii) Action by United States

In order to recover payment made under this subchapter for such an item or service, the United States may bring an action against any entity which is required or responsible (directly, as a third-party administrator, or otherwise) to make payment with respect to such item or service (or any portion thereof) under a primary plan (and may, in accordance with paragraph (3)(A) collect double damages against that entity), or against any other entity (including any physician or provider) that has received payment from that entity with respect to the item or service, and may join or intervene in any action related to the events that gave rise to the need or service. The United States may not recover from a third-party administrator under this clause in cases where the third-party administrator would not be able to recover the amount at issue from the employer or group health plan and is not employed by or under contract with the employer or group health plan at the time the action for recovery is initiated by the United States or for whom it provides administrative services due to the insolvency or bankruptcy of the employer or plan.

(iii) Subrogation rights

The United States shall be subrogated (to the extent of payment made under this subchapter for such an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

(iv) Waiver of rights

The Secretary may waive (in whole or in part) the provisions of this subparagraph in the case of an individual claim if the Secretary determines that the waiver is in the best interests of the program established under this subchapter.

(v) Claims-filing period

Notwithstanding any other time limits that may exist for filing a claim under an employer group health plan, the United States may seek to recover conditional payments in accordance with this subparagraph where the request for payment is submitted to the entity required or responsible under this subsection to pay with respect to the item or service (or any portion thereof) under a primary plan within the 3-year period beginning on the date on which the item or service was furnished.

(C) Treatment of questionnaires

The Secretary may not fail to make payment under subparagraph (A) solely on the ground that an individual failed to complete a questionnaire concerning the existence of a primary plan.

(3) Enforcement

(A) Private cause of action

There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with such paragraphs (1) and (2)(A).

(B) Reference to excise tax with respect to nonconforming group health plans

For provision imposing an excise tax with respect to nonconforming group health plans, see section 5000 of Title 26.

(C) Prohibition of financial incentives not to enroll in a group health plan or a large group health plan

It is unlawful for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits under this subchapter not to enroll (or to terminate enrollment) under a group health plan or a large group health plan which would (in the case of such enrollment) be a primary plan (as defined in paragraph (2)(A)). Any entity that violates the previous sentence is subject to a civil money penalty of not to exceed $5,000 for each such violation. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(4) Coordination of benefits

Where payment for an item or service by a primary plan is less than the amount of the charge for such item or service and is not payment in full, payment may be made under this subchapter (without regard to deductibles and coinsurance under this subchapter) for the remainder of such charge, but—

(A) payment under this subchapter may not exceed an amount which would be payable under this subchapter for such item or service if paragraph (2)(A) did not apply; and

(B) payment under this subchapter, when combined with the amount payable under the primary plan, may not exceed—

(i) in the case of an item or service payment for which is determined under this subchapter on the basis of reasonable cost (or other cost-related basis) or under section 1395ww of this title, the amount which would be payable under this subchapter on such basis, and

(ii) in the case of an item or service for which payment is authorized under this subchapter on another basis—

(I) the amount which would be payable under the primary plan (without regard to deductibles and coinsurance under such plan), or

(II) the reasonable charge or other amount which would be payable under this subchapter (without regard to deductibles and coinsurance under this subchapter),

whichever is greater.

(5) Identification of secondary payer situations

(A) Requesting matching information

(i) Commissioner of Social Security

The Commissioner of Social Security shall, not less often than annually, transmit to the Secretary of the Treasury a list of the names and TINs of medicare beneficiaries (as defined in section 6103(*l*)(12) of Title 26 and request that the Secretary disclose to the Commissioner the information described in subparagraph (A) of such section.

(ii) Administrator

The Administrator of the Health Care Financing Administration shall request, not less often than annually, the Commissioner of the Social Security Administration to disclose to the

Administrator the information described in subparagraph (B) of section 6103(*l*)(12) of Title 26.

(B) Disclosure to fiscal intermediaries and carriers

In addition to any other information provided under this subchapter to fiscal intermediaries and carriers, the Administrator shall disclose to such intermediaries and carriers (or to such a single intermediary or carrier as the Secretary may designate) the information received under subparagraph (A) for purposes of carrying out this subsection.

(C) Contacting employers

(i) In general

With respect to each individual (in this subparagraph referred to as an "employee") who was furnished a written statement under section 6051 of Title 26 by a qualified employer (as defined in section 6103(*l*)(12)(E)(iii) of such title), as disclosed under subparagraph (B), the appropriate fiscal intermediary or carrier shall contact the employer in order to determine during what period the employee or employee's spouse may be (or have been) covered under a group health plan of the employer and the nature of the coverage that is or was provided under the plan (including the name, address, and identifying number of the plan).

(ii) Employer response

Within 30 days of the date of receipt of the inquiry, the employer shall notify the intermediary or carrier making the inquiry as to the determinations described in clause (i). An employer (other than a Federal or other governmental entity) who willfully or repeatedly

fails to provide timely and accurate notice in accordance with the previous sentence shall be subject to a civil money penalty of not to exceed $1,000 for each individual with respect to which such an inquiry is made. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(D) Obtaining information from beneficiaries

Before an individual applies for benefits under part A of this subchapter or enrolls under part B of this subchapter, the Administrator shall mail the individual a questionnaire to obtain information on whether the individual is covered under a primary plan and the nature of the coverage provided under the plan, including the name, address, and identifying number of the plan.

(6) Screening requirements for providers and suppliers

(A) In general

Notwithstanding any other provision of this subchapter, no payment may be made for any item or service furnished under part B of this subchapter unless the entity furnishing such item or service completes (to the best of its knowledge and on the basis of information obtained from the individual to whom the item or service is furnished) the portion of the claim form relating to the availability of other health benefit plans.

(B) Penalties

An entity that knowingly, willfully, and repeatedly fails to complete a claim form in

accordance with subparagraph (A) or provides inaccurate information relating to the availability of other health benefit plans on a claim form under such subparagraph shall be subject to a civil money penalty of not to exceed $2,000 for each such incident. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

* * *

42 U.S.C. § 1395y
(incorporating December 2003 amendments)

§ 1395y. Exclusions from coverage and medicare as secondary payer

* * *

(b) Medicare as secondary payer

(1) Requirements of group health plans

(A) Working aged under group health plans

(i) In general

A group health plan—

(I) may not take into account that an individual (or the individual's spouse) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this subchapter under section 426(a) of this title, and

(II) shall provide that any individual age 65 or older (and the spouse age 65 or older of any individual) who has current employment status with an employer shall be entitled to the same benefits under the plan under the same conditions as any such individual (or spouse) under age 65.

(ii) Exclusion of group health plan of a small employer

Clause (i) shall not apply to a group health plan unless the plan is a plan of, or contributed to by, an employer that has 20 or more employees for each working day in each of 20 or more calendar weeks in the current calendar year or the preceding calendar year.

(iii) Exception for small employers in multiemployer or multiple employer group health plans

Clause (i) also shall not apply with respect to individuals enrolled in a multiemployer or multiple employer group health plan if the coverage of the individuals under the plan is by virtue of current employment status with an employer that does not have 20 or more individuals in current employment status for each working day in each of 20 or more calendar weeks in the current calendar year and the preceding calendar year; except that the exception provided in this clause shall only apply if the plan elects treatment under this clause.

(iv) Exception for individuals with end stage renal disease

Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 426 of this title) would upon application be, entitled to benefits under section 426-1 of this title.

(v) "Group health plan" defined

In this subparagraph, and subparagraph (C), the term "group health plan" has the meaning given such term in section 5000(b)(1) of the Internal Revenue Code of 1986, without regard to section 5000(d) of Title 26.

(B) Disabled individuals in large group health plans

(i) In general

A large group health plan (as defined in clause (iii)) may not take into account that an individual (or a member of the individual's

family) who is covered under the plan by virtue of the individual's current employment status with an employer is entitled to benefits under this subchapter under section 426(b) of this title.

(ii) Exception for individuals with end stage renal disease

Subparagraph (C) shall apply instead of clause (i) to an item or service furnished in a month to an individual if for the month the individual is, or (without regard to entitlement under section 426 of this title) would upon application be, entitled to benefits under section 426-1 of this title.

(iii) "Large group health plan" defined

In this subparagraph, the term "large group health plan" has the meaning given such term in section 5000(b)(2) of Title 26, without regard to section 5000(d) of Title 26.

(C) Individuals with end stage renal disease

A group health plan (as defined in subparagraph (A)(v))—

(i) may not take into account that an individual is entitled to or eligible for benefits under this subchapter under section 426-1 of this title during the 12-month period which begins with the first month in which the individual becomes entitled to benefits under part A under the provisions of section 426-1 of this title, or, if earlier, the first month in which the individual would have been entitled to benefits under such part under the provisions of section 426-1 of this title if the individual had filed an application for such benefits; and

(ii) may not differentiate in the benefits it provides between individuals having end stage

renal disease and other individuals covered by such plan on the basis of the existence of end stage renal disease, the need for renal dialysis, or in any other manner;

(D) Treatment of certain members of religious orders

In this subsection, an individual shall not be considered to be employed, or an employee, with respect to the performance of services as a member of a religious order which are considered employment only by virtue of an election made by the religious order under section 3121(r) of the Internal Revenue Code of 1986.

(E) General provisions

For purposes of this subsection:

(i) Aggregation rules

(I) All employers treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as a single employer.

(II) All employees of the members of an affiliated service group (as defined in section 414(m) of Title 26) shall be treated as employed by a single employer.

(III) Leased employees (as defined in section 414(n)(2) of Title 26) shall be treated as employees of the person for whom they perform services to the extent they are so treated under section 414(n) of Title 26.

In applying sections of the Internal Revenue Code of 1986 under this clause, the Secretary shall rely upon regulations and decisions of the Secretary of the Treasury respecting such sections.

(ii) Current employment status defined

An individual has "current employment status" with an employer if the individual is an employee, is the employer, or is associated with the employer in a business relationship.

(iii) Treatment of self-employed persons as employers

The term "employer" includes a self-employed person.

(F) Limitation on beneficiary liability

An individual who is entitled to benefits under this title and is furnished an item or service for which such benefits are incorrectly paid is not liable for repayment of such benefits under this paragraph unless payment of such benefits was made to the individual.

(2) Medicare secondary payer

(A) In general

Payment under this subchapter may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that—

(i) payment has been made, or can reasonably be expected to be made, with respect to the item or service as required under paragraph (1), or

(ii) payment has been made or can reasonably be expected to be made under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no fault insurance.

In this subsection, the term "primary plan" means a group health plan or large group health plan, to the extent that clause (i) applies, and a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured

plan) or no fault insurance, to the extent that clause (ii) applies. An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part.

(B) Repayment required

(i) Authority to make conditional payment

The Secretary may make payment under this subchapter with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.

(ii) Primary plans

A primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this subchapter with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means. If reimbursement is

not made to the appropriate Trust Fund before the expiration of the 60-day period that begins on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received, the Secretary may charge interest (beginning with the date on which the notice or other information is received) on the amount of the reimbursement until reimbursement is made (at a rate determined by the Secretary in accordance with regulations of the Secretary of the Treasury applicable to charges for late payments).

(iii) Action by United States

In order to recover payment made under this subchapter for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity. The United States may not recover from a third-party administrator under this clause in cases where the third-party administrator would not be able to recover the amount at issue from the employer or group health plan and is not employed by or under

contract with the employer or group health plan at the time the action for recovery is initiated by the United States or for whom it provides administrative services due to the insolvency or bankruptcy of the employer or plan.

(iv) Subrogation rights

The United States shall be subrogated (to the extent of payment made under this subchapter for such an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

(v) Waiver of rights

The Secretary may waive (in whole or in part) the provisions of this subparagraph in the case of an individual claim if the Secretary determines that the waiver is in the best interests of the program established under this subchapter.

(vi) Claims-filing period

Notwithstanding any other time limits that may exist for filing a claim under an employer group health plan, the United States may seek to recover conditional payments in accordance with this subparagraph where the request for payment is submitted to the entity required or responsible under this subsection to pay with respect to the item or service (or any portion thereof) under a primary plan within the 3-year period beginning on the date on which the item or service was furnished.

(C) Treatment of questionnaires

The Secretary may not fail to make payment under subparagraph (A) solely on the ground that an

individual failed to complete a questionnaire concerning the existence of a primary plan.

(3) Enforcement

(A) Private cause of action

There is established a private cause of action for damages (which shall be in an amount double the amount otherwise provided) in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with paragraphs (1) and (2)(A).

(B) Reference to excise tax with respect to nonconforming group health plans

For provision imposing an excise tax with respect to nonconforming group health plans, see section 5000 of Title 26.

(C) Prohibition of financial incentives not to enroll in a group health plan or a large group health plan

It is unlawful for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits under this subchapter not to enroll (or to terminate enrollment) under a group health plan or a large group health plan which would (in the case of such enrollment) be a primary plan (as defined in paragraph (2)(A)). Any entity that violates the previous sentence is subject to a civil money penalty of not to exceed $5,000 for each such violation. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(4) Coordination of benefits

Where payment for an item or service by a primary plan is less than the amount of the charge for such item or service and is not payment in full, payment may be made under this subchapter (without regard to deductibles and coinsurance under this subchapter) for the remainder of such charge, but—

(A) payment under this subchapter may not exceed an amount which would be payable under this subchapter for such item or service if paragraph (2)(A) did not apply; and

(B) payment under this subchapter, when combined with the amount payable under the primary plan, may not exceed—

(i) in the case of an item or service payment for which is determined under this subchapter on the basis of reasonable cost (or other cost-related basis) or under section 1395ww of this title, the amount which would be payable under this subchapter on such basis, and

(ii) in the case of an item or service for which payment is authorized under this subchapter on another basis—

(I) the amount which would be payable under the primary plan (without regard to deductibles and coinsurance under such plan), or

(II) the reasonable charge or other amount which would be payable under this subchapter (without regard to deductibles and coinsurance under this subchapter),

whichever is greater.

(5) Identification of secondary payer situations

(A) Requesting matching information

(i) Commissioner of Social Security

The Commissioner of Social Security shall, not less often than annually, transmit to the Secretary of the Treasury a list of the names and TINs of medicare beneficiaries (as defined in section 6103(*l*)(12) of the Internal Revenue Code of 1986) and request that the Secretary disclose to the Commissioner the information described in subparagraph (A) of such section.

(ii) Administrator

The Administrator of the Centers for Medicare & Medicaid Services shall request, not less often than annually, the Commissioner of the Social Security Administration to disclose to the Administrator the information described in subparagraph (B) of section 6103(*l*)(12) of the Internal Revenue Code of 1986.

(B) Disclosure to fiscal intermediaries and carriers

In addition to any other information provided under this subchapter to fiscal intermediaries and carriers, the Administrator shall disclose to such intermediaries and carriers (or to such a single intermediary or carrier as the Secretary may designate) the information received under subparagraph (A) for purposes of carrying out this subsection.

(C) Contacting employers

(i) In general

With respect to each individual (in this subparagraph referred to as an "employee") who was furnished a written statement under section 6051 of the Internal Revenue Code of 1986 by a qualified employer (as defined in section

6103(*l*)(12)(E)(iii) of such title), as disclosed under subparagraph (B), the appropriate fiscal intermediary or carrier shall contact the employer in order to determine during what period the employee or employee's spouse may be (or have been) covered under a group health plan of the employer and the nature of the coverage that is or was provided under the plan (including the name, address, and identifying number of the plan).

(ii) Employer response

Within 30 days of the date of receipt of the inquiry, the employer shall notify the intermediary or carrier making the inquiry as to the determinations described in clause (i). An employer (other than a Federal or other governmental entity) who willfully or repeatedly fails to provide timely and accurate notice in accordance with the previous sentence shall be subject to a civil money penalty of not to exceed $1,000 for each individual with respect to which such an inquiry is made. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(D) Obtaining information from beneficiaries

Before an individual applies for benefits under part A of this subchapter or enrolls under part B of this subchapter, the Administrator shall mail the individual a questionnaire to obtain information on whether the individual is covered under a primary plan and the nature of the coverage provided under

the plan, including the name, address, and identifying number of the plan.

(6) Screening requirements for providers and suppliers

(A) In general

Notwithstanding any other provision of this subchapter, no payment may be made for any item or service furnished under part B of this subchapter unless the entity furnishing such item or service completes (to the best of its knowledge and on the basis of information obtained from the individual to whom the item or service is furnished) the portion of the claim form relating to the availability of other health benefit plans.

(B) Penalties

An entity that knowingly, willfully, and repeatedly fails to complete a claim form in accordance with subparagraph (A) or provides inaccurate information relating to the availability of other health benefit plans on a claim form under such subparagraph shall be subject to a civil money penalty of not to exceed $2,000 for each such incident. The provisions of section 1320a-7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1320a-7a(a) of this title.

* * *

42 C.F.R. § 411.21

§ 411.21 Definitions

In this subpart B and in subparts C through H of this part, unless the context indicates otherwise—

Conditional payment means a Medicare payment for services for which another payer is responsible, made either on the bases set forth in subparts C through H of this part, or because the intermediary or carrier did not know that the other coverage existed.

Coverage or *covered services*, when used in connection with third party payments, means services for which a third party payer would pay if a proper claim were filed.

Monthly capitation payment means a comprehensive monthly payment that covers all physician services associated with the continuing medical management of a maintenance dialysis patient who dialyses at home or as an outpatient in an approved ESRD facility.

Plan means any arrangement, oral or written, by one or more entities, to provide health benefits or medical care or assume legal liability for injury or illness.

Prompt or *promptly*, when used in connection with third party payments, except as provided in § 411.50, for payments by liability insurers, means payment within 120 days after receipt of the claim.

Proper claim means a claim that is filed timely and meets all other claim filing requirements specified by the plan, program, or insurer.

Secondary, when used to characterize Medicare benefits, means that those benefits are payable only to the extent that payment has not been made and cannot reasonably be expected to be made under other coverage that is primary to Medicare.

Secondary payments means payments made for Medicare covered services or portions of services that are not payable under other coverage that is primary to Medicare.

Third party payer means an insurance policy, plan, or program that is primary to Medicare.

Third party payment means payment by a third party payer for services that are also covered under Medicare.

42 C.F.R. § 411.24

§ 411.24 Recovery of conditional payments.

If a Medicare conditional payment is made, the following rules apply:

(a) *Release of information.* The filing of a Medicare claim by on or behalf of the beneficiary constitutes an express authorization for any entity, including State Medicaid and workers' compensation agencies, and data depositories, that possesses information pertinent to the Medicare claim to release that information to CMS. This information will be used only for Medicare claims processing and for coordination of benefits purposes.

(b) *Right to initiate recovery.* CMS may initiate recovery as soon as it learns that payment has been made or could be made under workers' compensation, any liability or no-fault insurance, or an employer group health plan.

(c) *Amount of recovery—*

(1) If it is not necessary for CMS to take legal action to recover, CMS recovers the lesser of the following:

(i) The amount of the Medicare primary payment.

(ii) The full primary payment amount that the primary payer is obligated to pay under this part without regard to any payment, other than a full primary payment that the primary payer has paid or will make, or, in the case of a third party payment recipient, the amount of the third party payment.

(2) If it is necessary for CMS to take legal action to recover from the primary payer, CMS may recover twice the amount specified in paragraph (c)(1)(i) of this section.

(d) *Methods of recovery.* CMS may recover by direct collection or by offset against any monies CMS owes the entity responsible for refunding the conditional payment.

(e) *Recovery from third parties.* CMS has a direct right of action to recover from any entity responsible for making primary payment. This includes an employer, an insurance carrier, plan, or program, and a third party administrator.

(f) *Claims filing requirements.* (1) CMS may recover without regard to any claims filing requirements that the insurance program or plan imposes on the beneficiary or other claimant such as a time limit for filing a claim or a time limit for notifying the plan or program about the need for or receipt of services.

(2) However, CMS will not recover its payment for particular services in the face of a claims filing requirement unless it has filed a claim for recovery by the end of the year following the year in which the Medicare intermediary or carrier that paid the claim has notice that the third party is primary to Medicare for those particular services. (A notice received during the last three months of a year is considered received during the following year.)

(g) *Recovery from parties that receive third party payments.* CMS has a right of action to recover its payments from any entity, including a beneficiary, provider, supplier, physician, attorney, State agency or private insurer that has received a third party payment.

(h) *Reimbursement to Medicare.* If the beneficiary or other party receives a third party payment, the beneficiary or other party must reimburse Medicare within 60 days.

(i) *Special rules.* (1) In the case of liability insurance settlements and disputed claims under employer group health plans and no-fault insurance, the following rule applies: If Medicare is not reimbursed as required by paragraph (h) of this section, the third party payer must reimburse Medicare even though it has already reimbursed the beneficiary or other party.

(2) The provisions of paragraph (i)(1) of this section also apply if a third party payer makes its payment to an entity

other than Medicare when it is, or should be, aware that Medicare has made a conditional primary payment.

(3) In situations that involve procurement costs, the rule of § 411.37(b) applies.

(j) *Recovery against Medicaid agency.* If a third party payment is made to a State Medicaid agency and that agency does not reimburse Medicare, CMS may reduce any Federal funds due the Medicaid agency (under title XIX of the Act) by an amount equal to the Medicare payment or the third party payment, whichever is less.

(k) *Recovery against Medicare contractor.* If a Medicare contractor, including an intermediary or carrier also insures, underwrites, or administers as a third party administrator, a program or plan that is primary to Medicare, and does not reimburse Medicare, CMS may offset the amount owed against any funds due the intermediary or carrier under title XVIII of the Act or due the contractor under the contract.

(*l*) *Recovery when there is failure to file a proper claim*—(1) Basic rule. If Medicare makes a conditional payment with respect to services for which the beneficiary or provider or supplier has not filed a proper claim with a third party payer, and Medicare is unable to recover from the third party payer, Medicare may recover from the beneficiary or provider or supplier that was responsible for the failure to file a proper claim.

(2) Exceptions: (i) This rule does not apply in the case of liability insurance nor when failure to file a proper claim is due to mental or physical incapacity of the beneficiary.

(ii) CMS will not recover from providers or suppliers that are in compliance with the requirements of § 489.20 of this chapter and can show that the reason they failed to file a proper claim is that the beneficiary, or someone acting on his or her behalf, failed to give, or gave erroneous, information regarding coverage that is primary to Medicare.

(m) *Interest charges.* (1) With respect to recovery of payments for items and services furnished before October 31, 1994, CMS charges interest, exercising common law authority in accordance with 45 CFR 30.13, consistent with the Federal Claims Collection Act (31 U.S.C. 3711).

(2) In addition to its common law authority with respect to recovery of payments for items and services furnished on or after October 31, 1994, CMS charges interest in accordance with section 1862(b)(2)(B)(i) of the Act. Under that provision—

(i) CMS may charge interest if reimbursement is not made to the appropriate trust fund before the expiration of the 60-day period that begins on the date on which notice or other information is received by CMS that payment has been or could be made under a primary plan;

(ii) Interest may accrue from the date when that notice or other information is received by CMS and is charged until reimbursement is made; and

(iii) The rate of interest is that provided at 42 CFR 405.376(d).

42 C.F.R. § 411.25

§ 411.25 Third party payer's notice of mistaken Medicare primary payment.

(a) If a third party payer learns that CMS has made a Medicare primary payment for services for which the third party payer has made or should have made primary payment, it must give notice to that effect to the Medicare intermediary or carrier that paid the claim.

(b) The notice must describe the specific situation and the circumstances (including the particular type of insurance coverage as specified in § 411.20(a)) and, if appropriate, the time period during which the insurer is primary to Medicare.

(c) If a plan is self-insured and self-administered, the employer must give the notice to CMS. Otherwise, the insurer, underwriter, or third party administrator must give the notice.

42 C.F.R. § 411.50

§ 411.50 General provisions.

(a) Limits on applicability. The provisions of this Subpart C do not apply to any services required because of accidents that occurred before December 5, 1980.

(b) Definitions.

Automobile means any self-propelled land vehicle of a type that must be registered and licensed in the State in which it is owned.

Liability insurance means insurance (including a self-insured plan) that provides payment based on legal liability for injury or illness or damage to property. It includes, but is not limited to, automobile liability insurance, uninsured motorist insurance, underinsured motorist insurance, homeowners' liability insurance, malpractice insurance, product liability insurance, and general casualty insurance.

Liability insurance payment means a payment by a liability insurer, or an out-of-pocket payment, including a payment to cover a deductible required by a liability insurance policy, by any individual or other entity that carries liability insurance or is covered by a self-insured plan.

No-fault insurance means insurance that pays for medical expenses for injuries sustained on the property or premises of the insured, or in the use, occupancy, or operation of an automobile, regardless of who may have been responsible for causing the accident. This insurance includes but is not limited to automobile, homeowners, and commercial plans. It is sometimes called medical payments coverage, personal injury protection, or medical expense coverage.

Prompt or promptly, when used in connection with payment by a liability insurer means payment within 120 days after the earlier of the following:

(1) The date a claim is filed with an insurer or a lien is filed against a potential liability settlement.

(2) The date the service was furnished or, in the case of inpatient hospital services, the date of discharge.

Self-insured plan means a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier. The term includes a plan of an individual or other entity engaged in a business, trade, or profession, a plan of non-profit organization such as a social, fraternal, labor, educational, religious, or professional organization, and the plan established by the Federal government to pay liability claims under the Federal Tort Claims Act.

Underinsured motorist insurance means insurance under which the policyholder's level of protection against losses caused by another is extended to compensate for inadequate coverage in the other party's policy or plan.

Uninsured motorist insurance means insurance under which the policyholder's insurer will pay for damages caused by a motorist who has no automobile liability insurance or who carries less than the amount of insurance required by law, or is underinsured.

(c) Limitation on payment for services covered under no-fault insurance. Except as provided under §§ 411.52 and 411.53 with respect to conditional payments. Medicare does not pay for the following:

(1) Services for which payment has been made or can reasonably be expected to be made promptly under automobile no-fault insurance.

(2) Services furnished on or after November 13, 1989 for which payment has been made or can reasonably be

expected to be made promptly under any no-fault insurance other than automobile no-fault.

R.1

IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA

Case No. CV-00–BU–0837-S

The United States, Plaintiff
v.
Baxter International Inc., Baxter Healthcare Corporation, Bristol-Meyers Squibb Company, Minnesota Mining & Manufacturing Co. A/K/A 3M Company, Union Carbide, Chemical & Plastics Co., Union Carbide Corporation, and Edgar C. Gentle, III, in his official capacity as the Escrow Agent for the Settlement Fund established in In Re Silicone Gel Breast Implant Products Liability Litigation (MDL 926), No. CV-92-1000-S) (N.D. Ala.), Defendants.

[Filed: 00 Mar 31 AM 9:54
U.S. District Court
N.D. of Alabama]

COMPLAINT

The United States of America files this civil action to recover costs of medical care provided or paid for by the United States, based upon rights conferred under two federal statutes: (1) the Medicare Secondary Payer ("MSP") statute, 42 U.S.C. § 1395y(b)(2), and regulations promulgated thereunder, 42 C.F.R. part 411, pursuant to which the United States may recover conditional Medicare payments from defendants who are primarily liable to make these payments; and (2) the Medical Care Recovery Act, 42 U.S.C. §§ 2651-53 ("MCRA"), pursuant to which the United States may recover the reasonable value of medical care

provided to or paid for by the United States on behalf of a person whose illness or injury arose from circumstances creating a tort liability in a third party. In support of its complaint, the United States makes the following allegations:

PARTIES

1. The United States files this lawsuit:

(a) pursuant to the MSP statute, on behalf of the Secretary of Health and Human Services ("HHS"). The Secretary of HHS is the federal official vested with primary responsibility for oversight of the Medicare program, which provides health insurance benefits to specified elderly and disabled individuals pursuant to 42 U.S.C. § 1395. The Secretary has delegated responsibility for administration of the Medicare benefits program to the Health Care Financing Administration ("HCFA"). 42 U.S.C. §§ 1935hh and ii.

(b) pursuant to the MCRA, on behalf of HCFA and the Departments of Defense ("DOD"), Veterans Affairs ("VA") and the Indian Health Service ("IHS") of HHS.

2. Upon information and belief, Baxter Healthcare Corporation is a Delaware corporation with its principal place of business in Illinois, and Baxter International, Inc. is a Delaware corporation with its principal place of business in Illinois (collectively "Baxter").

3. Upon information and belief, Bristol-Myers Squibb Company ("Bristol") is a Delaware corporation with its principal place of business in New York.

4. Upon information and belief, defendant Minnesota Mining and Manufacturing Company, a/k/a 3M, is a Delaware corporation with its principal place of business in California.

5. Upon information and belief, defendant 3M has assumed the liabilities of McGhan Medical Corporation, a/k/a McGhan Medical/3M, formally a Delaware corporation with

its principal place of business in California, for products manufactured by McGhan before August 3, 1984.

6. Upon information and belief, defendant Union Carbide Chemical and Plastics Company Inc., a/k/a Union Carbide Corporation, is a New York corporation with its principal place of business in California.

7. Upon information and belief, Edgar C. Gentle, III (the "Escrow Agent") is the duly appointed Escrow Agent of the settlement fund established pursuant to Orders No. 13 (July 23, 1993), No. 15 (April 1, 1994), and No. 27 (December 22, 1995) in In re Silicone Gel Breast Implants Products Liability Litigation (MDL 926), Civ. No. 92-P-1000-S (N.D. Ala.) (the "MDL" and the "MDL Settlement Fund"). Upon information and belief, the MDL Settlement Fund consists of a number of funds including a plaintiffs' litigation expense fund to pay common expenses of benefit to the entire class (the "Common Benefit Fund") and a fund maintained to pay benefits under the Revised Settlement Program (the "RSP Settlement Fund").

JURISDICTION AND VENUE

8. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1345, 28 U.S.C. § 2201, the MSP statute, 42 U.S.C. § 1395y(b)(2), and the MCRA, 42 U.S.C. §§ 2651-53.

9. This action is brought in this district pursuant to 28 U.S.C. § 1407, because this action is related to In re Silicone Gel Breast Implant Products Liability Litigation (MDL 926).

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(B)(3).

FACTUAL ALLEGATIONS

Breast Implant Litigation—The Multi-District Litigation

11. On April 1, 1994, the district court for the Northern District of Alabama, Judge Sam C. Pointer, Jr., provisionally certified a class action, for settlement purposes, of individual

breast implant claimants who alleged that they suffered injuries as a result of having been implanted with breast implants ("Claimants"). Lindsey v. Dow Corning Corp., No. CV 94-P-11558-S (N.D. Ala.) (MDL Order No. 15 April 1, 1994).

12. As used herein, breast implants are defined as "any mammary prosthesis containing or consisting of silicone, silicone gel, polyurethane or polyurethane covering, an elastomer made of silicone and/or a saline-filled silicone envelope, that were manufactured, distributed, designed, fabricated, sold, produced or otherwise placed in the stream of commerce ..." by any defendant in this case. See Lindsey Complaint, at ¶1.

13. In the Lindsey Complaint, Claimants alleged that a number of entities, including Bristol, Baxter, 3M and Union Carbide, by their actions or inactions, proximately caused Claimants' injuries. Id.

14. In the Lindsey Complaint, Claimants alleged that Bristol, Baxter, 3M and Union Carbide, among others, are liable to Claimants for their injuries resulting from having been implanted with breast implants. Id., at ¶¶55-85.

The MDL Settlement Program

15. On December 22, 1995, in Order No. 27, the Court approved the "Bristol, Baxter, 3M, McGhan and Union Carbide Revised Settlement Program" (the "RSP" and collectively, the "RSP Defendants"). The RSP's benefits to class members include a $3,000 payment to defray the cost of explant surgery and additional benefits for those Claimants with diseases or injuries allegedly caused by breast implants.

16. Order No. 27 approving the RSP established a fund pursuant to which "[e]ach settling defendant will pay into the fund ... such amounts as, from time to time during the 15 year period of the program, are estimated ... to be needed ... to pay benefits ..." Order No. 27, ¶J.

17. Upon information and belief, the RSP Defendants have paid monies into the MDL Settlement Fund, and will continue from time to time during the fifteen year duration of the RSP to pay additional monies into the MDL Settlement Fund. Order No. 27, ¶J.

18. Claimants may obtain payments from the RSP "without any need to establish any causal link between their breast implants and the disease or condition for which benefits are sought." Opening Memorandum of Certain Settling Defendants in Support of Final Approval of Breast Implant Settlement Agreement, MDL 926, p. 41.

19. Upon information and belief, as of April 1999, approximately 81,000 Claimants had been sent advance payments from the MDL Settlement Fund, and approximately 17,000 of these Claimants also received a $3,000 payment for an explant surgery. Approximately 26,800 of the 81,000 Claimants had also received payment for a breast implant-related disease, and another approximately 10,000 received a one-time payment of $2,500 and released all potential future claims arising from implant-related diseases and illnesses. See MDL 926 Breast Implant Litigation home page (www.fjc.gov/BREIMLIT/mdl926).

20. Upon information and belief, as of May 15, 1999, a total of 52,118 breast implant recipients had exercised the right to opt out of the Lindsey class ("Opt Out Claimants"). Of those, over 10,000 had submitted satisfactory proof of having Bristol, Baxter or 3M implants. See MDL 926 Breast Implant Litigation home page (www.fjc.gov/BREIMLIT/mdl926).

Additional Opt-out Settlements and Non-MDL Payments

21. Upon information and belief, the RSP Defendants also entered into settlements with many of these opt-out Claimants ("opt-out settlements"). See MDL 926 Breast Implant Litigation home page (www.fjc.gov/BREIMLIT/mdl926).

22. Upon information and belief, independent of the Lindsey class action and the RSP, the RSP Defendants settled with or paid judgments for breast implant claims (the "non-MDL payments").

The MDL Common Benefit Fund

23. Under the terms of Orders No. 13, 15 and 27 from the MDL court, the RSP Defendants must pay, and have paid, a six percent surcharge upon settlement amounts paid pursuant to the RSP. The surcharge is designated as the Common Benefit Fund, and held as part of the MDL Settlement Fund.

24. In addition to the surcharge paid upon all RSP settlement amounts, all Claimants who settle or recover a judgment in federal court pay six percent of their gross monetary recovery into the Common Benefit Fund. Notice of Revised Settlement Program, ¶28(b).

25. In Order No. 13A (December 28, 1999), the Court ordered a pro-rata "rebate" to Claimants of excess funds in the Common Benefit Fund, consistent with Order No. 13, ¶3(d), and the Notice of Revised Settlement Program, ¶28(c). All Claimants to whom the surcharge was applied will receive a payment equal to 1/3 of the amount initially assessed. In addition, in all future settlements under the RSP, Claimants will receive an additional payment equal to 1/3 of the six percent assessment paid by an RSP Defendant. Upon information and belief, the total amount of these payments will exceed $5 million.

Medicare's Conditional Payments and Causes of Action

26. The United States, through HCFA as the administrator of the Medicare program, has paid for medical care related to breast implants on behalf of thousands of women. Upon information and belief, some of the Claimants who received compensation from the RSP Defendants on account of breast implants are among those for whom Medicare made these payments.

27. A series of statutes known collectively and codified the MSP statute, 42 U.S.C. § 1395y(b), requires available private insurance, including self insurance, to make the primary payment for services provided to Medicare beneficiaries, leaving Medicare to pay only secondary benefits. The law provides, in pertinent part, that

> payment under this subchapter may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that ... payment has been made or can reasonably be expected to be made promptly ... under a ... liability insurance policy or plan (including a self-insured plan) ...

42 U.S.C. § 1395y(b)(2)(A)(ii) ; see 42 C.F.R. § 411.20(a)(ii).

28. A Medicare payment is "conditional" when another payer is responsible to pay. 42 C.F.R. § 411.21. The United States has the right to recover conditional Medicare payments "when notice or other information is received that payment for such item has been or could be made under" a pertinent plan or policy. 42 U.S.C. § 1395y(b)(2)(B)(ii); see also 42 C.F.R. § 411. 24 (e) & (g)

29. The United States may bring an action to recover Trust Funds paid by Medicare for an item or service, against "any entity which is required or responsible ... to make payments with respect to such item or service (or any portion thereof) under a primary plan ... or against any other entity ... that has received payment from that entity ..." 42 U.S.C. 1395y(b)(2)(B)(ii). The regulations provide HCFA with a right to initiate recovery of conditional payments. 42 C.F.R. § 411.24.

30. HCFA may seek reimbursement when payment can reasonably be expected to be made promptly under a primary plan, including "an automobile or liability insurance policy or plan (including a self-insured plan) or under no

fault insurance." 42 U.S.C. § 1395y(b)(2)(A)(ii) ; 42 C.F.R. §§ 411.24(e); 411.50(b).

31. A third party payer is defined in the regulations as an insurance policy, plan (including any arrangement, oral or written, to provide health benefits or assume legal liability for injury or illness), or program that is primary to Medicare. 42 C.F.R. § 411.21.

32. A third party payer is required to reimburse Medicare even if it has already paid a beneficiary or other party. 42 C.F.R. § 411.24(i). A liability insurer is required to reimburse Medicare regardless of whether or not it was aware of Medicare's conditional payment at the time it paid the beneficiary or other party. 42 C.F.R. § 411.24(i)(1).

33. The United States may collect double damages from any entity responsible to make payment under a primary plan which fails to provide for primary payment or appropriate reimbursement to the United States. 42 U.S.C. § 1395y(b)(2)(B)(ii) ; 42 C.F.R. § 411.24(c)(2) .

34. Any entity that has "received a third party payment" must also reimburse Medicare within 60 days of its receipt. 42 U.S.C. § 1395y(b)(2)(B) ; 42 C.F.R. § 411.24 (g)&(h) .

35. In addition to its direct right of action, the United States is subrogated to any right of any individual or any other entity to payment under a primary plan (including a liability insurance policy or plan or a self-insured plan). 42 U.S.C. § 1395y(b)(2)(B)(iii).

36. Upon information and belief, in addition or in the alternative, the RSP Defendants received payments from liability insurers in order to pay breast implant-related claims and judgments.

RSP Defendants' Failure to Comply with the MSP Statute

37. Upon information and belief, the RSP Defendants are third party payers as defined in the MSP statute and

regulations. Upon information and belief, the RSP Defendants made payments on account of breast implant claims to the MDL Settlement Fund, including to the Common Benefit Fund, and/or directly to Claimants.

38. RSP Defendants, as third party payers, are obliged to provide information to HCFA when they learn that Medicare made primary payment for services for which the third party should have paid primary. 42 C.F.R. § 411.25(a). The release to HCFA of such information held by any entity is expressly authorized if pertinent to a claim for repayment of a conditional Medicare payment. 42 C.F.R. § 411.24(a).

39. Upon information and belief, the RSP Defendants did not ascertain whether any Claimant was a Medicare beneficiary prior to making, or causing to be made, opt out settlement payments or non-MDL payments to Claimants.

40. The RSP Defendants made no payment to the United States on behalf of any Claimants who obtained opt-out settlement payments or non-MDL payments, and whose medical care was paid for by the Medicare program.

41. Upon information and belief, the RSP Defendants did not ascertain whether any Claimant who obtained payment through the MDL Settlement Fund was a Medicare beneficiary, prior to making such payments or causing such payments to be made.

42. The RSP Defendants made no payment to the United States on behalf of any Claimant who obtained payment through the MDL Settlement Fund, including through the RSP, and whose medical care was paid for by the Medicare program.

RSP Defendants' Insurance

43. Upon information and belief, the RSP Defendants were self-insured against the risk of products liability claims by breast implant recipients, and paid such claims from self-insured funds or retained earnings.

44. In the alternative or in addition, upon information and belief, the RSP Defendants were self-insured in part against the risk of products liability claims by breast implant recipients, and paid such claims from self-insured funds or retained earnings.

45. In the alternative or in addition, upon information and belief, the RSP Defendants purchased liability insurance against the risk of products liability litigation that covered, in whole or in part, the claims made by breast implant recipients.

46. Upon information and belief, the RSP Defendants did pay with insurance proceeds, or cause their insurers to pay, claims made by breast implant recipients.

Escrow Agent's Failure to Comply with the MSP Statute

47. Upon information and belief, Edgar Gentle, in his capacity as Escrow Agent of the MDL Settlement Fund, received payments from the RSP Defendants and/or their insurers in order to pay breast implant-related claims.

48. Upon information and belief, the Escrow Agent did not ascertain whether any Claimant was a Medicare beneficiary prior to making or causing to be made payments to Claimants.

49. The Escrow Agent has made no payment to the United States on behalf of any Clamant who obtained payment through the MDL Settlement Fund, and whose medical care was paid for by the Medicare program.

The Medical Care Recovery Act

50. Persons who receive medical care provided or paid for by the United States under circumstances in which a third party may be liable in tort are required to furnish information to the United States concerning the injury and concerning any action instituted against the third party. 28 C.F.R. § 43.2. Pursuant to this same regulation, persons who receive such medical care from the United States are required to cooperate in the prosecution of all claims by the

United States against that third party, and to notify the United States of a settlement with, or an offer of settlement from, a third person. Id.

51. Upon information and belief, the United States, through HCFA, DoD, VA and IHS, has and will in the future, furnish or pay for hospital, medical, surgical or dental care and treatment to Claimants who were or will be compensated through the MDL Settlement Fund for injuries alleged to be caused by breast implants.

52. Upon information and belief, the RSP Defendants agreed to compensate Claimants for all compensatory and bodily injury allegedly caused by the RSP Defendants' breast implants and obtained in return a complete and unconditional release of these claims.

53. Upon information and belief, pursuant to the RSP, the RSP Defendants paid, or caused their insurers to pay the MDL Settlement Fund in order to compensate Claimants who allege injuries or diseases caused by the RSP Defendants' breast implants.

54. Upon information and belief, the Escrow Agent holds funds, a portion of which relate to Claimants whose medical care was furnished or paid for by the United States.

Notification of the United States

55. HCFA has been notified, by persons other than the defendants herein, of several hundred instances in which individual Medicare beneficiaries received payment for breast implant related injuries for which Medicare also made conditional payments. Upon information and belief, these cases represent only a fraction of the instances in which Medicare made such an unreimbursed conditional payment.

56. DoD, VA and IHS have been notified, by persons other than the defendants herein, of several instances in which individuals who received medical care provided or paid for by the United States under circumstances in which

the MCRA may apply anticipate entering into settlements of their breast implant-related claims. Upon information and belief, these cases represent only a fraction of the instances in which the affected agency provided or paid for medical care for a Claimant.

Count I (Against RSP Defendants as Third Party Payers)

57. The United States repeats and incorporates the allegations in paragraphs 1 through 56, above.

58. The RSP Defendants are required to pay the United States for conditional Medicare payments made on behalf of Claimants for breast implant-related items or services to the extent that the RSP Defendants also compensate these Claimants for these alleged injuries.

59. HCFA claims reimbursement from Bristol, Baxter, 3M and Union Carbide as third party payers liable under the MSP statute, and demands payment of the amount of its conditional Medicare payments, plus interest.

Count II (Double Damages Against RSP Defendants as Third Party Payers)

60. The United States repeats and incorporates the allegations in paragraphs 1 through 56, above.

61. The RSP Defendants are required to pay the United States for conditional Medicare payments made on behalf of Claimants for breast implant-related items or services to the extent that the RSP Defendants also compensate these Claimants for these alleged injuries.

62. HCFA claims reimbursement from Bristol, Baxter, 3M and Union Carbide as third party payers liable under the MSP statute, and demands payment of double the amount of its conditional Medicare payments, plus interest, because it has been necessary to initiate this suit. 42 U.S.C. § 1395y(b)(3), 42 C.F.R. § 411.24(c)(2).

Count III (Single Damages Against RSP Defendants as Entities That Received Payment)

63. The United States repeats and incorporates the allegations in paragraphs 1 through 56, above.

64. In the alternative, the RSP Defendants received payments from product liability insurers or caused such payments to be made in order to compensate Claimants for their alleged breast implant-related injuries.

65. Bristol, Baxter, 3M and Union Carbide are entities that received payment from a third party payer liable under the MSP statute, and are required to pay the United States damages in the amount of HCFA's conditional payments, plus interest.

Count IV (Right to Receive Payments as Subrogee)

66. The United States repeats and incorporates the allegations in paragraphs 1 through 56, above.

67. The United States is subrograted to the right of Claimants who are Medicare beneficiaries to receive payment from the MDL Settlement Fund and/or from the Common Benefit Fund. 42 U.S.C. § 1395(b)(2)(B)(iii).

68. HCFA claims reimbursement as a subrogee of those Claimants who are Medicare beneficiaries and demands repayment of its conditional Medicare payments from all future disbursements from the MDL Settlement Fund and/or the Common Benefit Fund.

Count V (Declaratory Relief)

69. The United States repeats and incorporates the allegations in paragraphs 1 through 56, above.

70. Pursuant to 28 U.S.C. § 2201, and Fed. R. Civ. P. 57, the United States is entitled to a Declaration as follows:

a. that to the extent HCFA has not previously been reimbursed, the RSP Defendants are liable to reimburse HCFA for past payments made to breast implant Claimants, whether through the

RSP, as opt-out settlement payments, or non-MDL payments, in accord with the terms of the MSP statute;

b. that the RSP Defendants must give HCFA notice of all payments to Medicare beneficiaries pursuant to 42 C.F.R. § 411.25; and

c. that all defendants must ensure before payment is made to any Claimant that appropriate payment is made to the United States.

Count VI (Damages From Escrow Agent of MDL Settlement Fund)

71. The United States repeats and incorporates the allegations in paragraphs 1 through 56, above.

72. Edgar Gentle, as Escrow Agent, received payment from the RSP Defendants and/or their product liability insurers to pay Claimants for breast implant related claims.

73. Edgar Gentle, as Escrow Agent, is an entity that received payment within the meaning of the MSP statute.

74. Edgar Gentle, as Escrow Agent, is required to pay the United States the amount of Medicare's conditional payments prior to making any distribution to Claimants, their attorneys, or any other party.

Count VII (Injunctive Relief Pertaining to Payments Subject to the MSP Statute)

75. The United States repeats and incorporates the allegations in paragraphs 1 through 56, above.

76. The United States is entitled to an order of this Court enjoining Edgar Gentle, as Escrow Agent, from making any further payments from the Common Benefit Fund, as ordered in Order No. 13A, to Claimants who are Medicare beneficiaries pending resolution of the United States' claims under the MSP statute.

77. The United States is entitled to an order enjoining Edgar Gentle, as Escrow Agent, from making any further

payments to Claimants who are Medicare beneficiaries pending inquiry into the Medicare eligibility of any Claimants; and further, to an order enjoining any disbursements to Claimants who are found to have been eligible for Medicare benefits, pending resolution of the United States' claims under the MSP statute.

78. The United States is entitled to disclosure of identities and additional information concerning all payments made, or contemplated to be made, by the RSP Defendants or the MDL Settlement Fund to Claimants who are or have been Medicare beneficiaries. 42 C.F.R. § 411.25.

79. The United States is entitled to an order of this court implementing procedures to ensure that the United States' claims under the MSP statute are provided for prior to disbursement of further funds from the MDL Settlement Fund.

Count VIII (Injunctive Relief Pertaining to Payments Subject to the Medical Care Recovery Act)

80. The United States repeats and incorporates the allegations in paragraphs 1 through 56, above.

81. The United States is entitled to an order of this Court enjoining Edgar Gentle, as Escrow Agent, from making any further payments from the Common Benefit Fund, as ordered in Order No. 13A, to Claimants who are eligible for medical care furnished or paid for by the United States pending resolution of the United States' claims under the MCRA.

82. The United States is entitled to an order of this Court requiring disclosure of the identities of persons who were, or will be, compensated by the RSP Defendants or the MDL Settlement Fund for a breast implant-related claim and who also received medical care provided or paid for by the United States that is related to a breast implant injury.

83. The United States is entitled to an order enjoining the Escrow Agent from making any further payments to

Claimants pending inquiry into the eligibility of any Claimants for medical care provided to or paid for by the United States; and further to an order enjoining any disbursements to Claimants who are found to have been eligible for such medical care, pending resolution of the United States' claims under the MCRA.

84. The United States is entitled to an order of this Court enjoining the Escrow Agent from making payments from the Common Benefit Fund to Claimants who received medical care provided to by or paid for by the United States, pending resolution of the United States' claims under the MCRA.

85. The United States is entitled to an order of this court implementing procedures to ensure that the United States' claims under the MCRA are provided for prior to disbursement of further funds from the MDL Settlement Fund.

Count IX (Demand for Payment from the MDL Settlement Fund Pursuant to MCRA)

86. The United States repeats and incorporates the allegations in paragraphs 1 through 56, above.

87. Upon information and belief, paragraph K.4. of the RSP purports to create an indemnity of the RSP Defendants by Claimants against the claims of the United States pursuant to the MSP statute and MCRA.

88. Upon information and belief, paragraph K.4. of the RSP agreement provides that amounts the RSP Defendants pay to the MDL Settlement Fund are the only payments to be made with respect to the claims of the United States.

89. Upon information and belief, the Escrow Agent has paid, and will in the future pay, Claimants who allege that the RSP Defendants are liable in tort for the Claimants' breast implant-related injuries.

90. Upon information and belief, payments to Claimants from the MDL Settlement Fund compensate Claimants for alleged injury and disease caused by breast implants.

91. Pursuant to the MCRA, the United States demands payments from the MDL Settlement Fund of its reasonable costs of providing to or paying for hospital, medical, surgical or dental care on behalf of Claimants who were, or will be paid through the MDL Settlement Fund and/or the Common Benefit Fund for injuries alleged to be caused by a breast implant.

Prayer For Relief

The United States respectfully demands payment of damages as specified herein; interest, the issuance of an injunction forbidding the payment of funds from the MDL Settlement Fund pending resolution of this suit; declaratory relief, and any other relief this Court deems just and proper.

Dated: March 30, 2000

DAVID W. OGDEN
Acting Assistant Attorney General

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R.47 Exhibit 10

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

Master File No. CV-92-N-10000-S,
Civil Action No. CV-94-P-1158-S

In re: Silicone Gel Breast Implants Products Liability Litigation (MDL 926), Heidi Lindsey, et al.

FINAL ORDER AND JUDGMENT (Corrected)

* * *

The parties have, however, overreached in attempting, primarily in Section III.G of their agreement, to preclude all subrogation claims not only against the Settling Defendants but also against the settlement fund and class members receiving benefits under the Settlement. While it is proper to preclude further claims against the Settling Defendants by such subrogation claimants—who have not demonstrated that the proposed settlement should be disapproved as inadequate—nevertheless these claimants cannot be deprived at this time, without their consent and without an opportunity to present their claims, of such rights they may have to pursue and perhaps intercept, in whole or in part, the benefits that may become payable to individual members of the class. The court's approval of this settlement should not be understood as approving those provisions or as denying such potential subrogation rights.

What rights, if any, different subrogation claimants may have is a matter yet to be determined. These questions

may depend not only on the particular contracts or statutes under which these claims are made, but also on the particular law to be applied.[23] These claims will also necessarily depend upon a determination of the benefits payable to particular members of the class.

To delve into these difficult issues at this time—before the defendants' "walk-away" decisions or the outcome of any appellate proceedings are known, and before any determination of potential benefits to class members has been made—is premature and involves potentially wasteful expenditures of time and money. In denying these motions to intervene on the basis of timeliness, the court did so not because they came too late, but because they are too early. The court will consider these issues at a later time, before any distributions (other than perhaps emergency distributions under Fund V) are made, and hopefully on the basis of motions that in some appropriate manner identify the persons on whose behalf subrogation claimants have paid medical expenses, rather than simply assert a general claim against the class.

* * *

This the 1st day of September, 1994.

/s/ Sam C. Pointer, Jr.
United States District Judge

---

[23] In earlier presentations, Settlement Class Counsel have argued that most, if not all, subrogation claims could be defeated. The court has not ruled on the merits of these arguments or the contrary arguments by subrogation claimants.

R.29 Exhibit A

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In re: SILICONE GEL BREAST IMPLANT PRODUCTS LIABILITY LITIGATION (MDL 926)
Master File No. CV 92-P-10000-S,

HEIDI LINDSEY, et al., Plaintiffs;

-vs-

DOW CORNING CORPORATION, et al., Defendants.
Civil Action No. CV 94-P-11558-S

[ENTERED: Dec 22 1995]

ORDER No. 27
(Approval of Revised Settlement Program and Injunctions)

It is hereby ORDERED as follows:

1. Attached to this order is the "Bristol, Baxter, 3M, McGhan & Union Carbide Revised Settlement Program," which has been submitted to the Court by such defendants in accordance with paragraph 18 of the notice that described the settlement which was approved on September 1, 1994 ("the Settlement").

* * *

This the 22nd day of December, 1995.

/s/ Sam C. Pointer, Jr.
Chief Judge

Bristol, Baxter, 3M, McGhan & Union Carbide Revised Settlement Program

* * *

J. Funding. Each settling defendant will pay into the fund established by the court such amounts as, from time to time during the 15 year period of the program, are estimated by the court with the assistance of the Claims Office to be needed (after considering undistributed funds previously contributed to the fund by that defendant) to pay benefits (or instalments) for which that settling defendant will become obligated to pay during the next 3 months. The fund will maintain appropriate records defining amounts contributed and disbursed with respect to each settling defendant and with respect to the Current Claimant and Other Registrant programs. The obligations of the defendants to contribute to funding of Option Two under E2 (except as specified in D2b(1)) are limited to annual cumulative amounts indicated in E2c above. As an initial reserve, Bristol, Baxter, and 3M will each pay into the fund by January 15, 1996, at least $125,000,000.

K. Miscellaneous

* * *

4. Subrogation-type claims by insurers or governmental agencies based on payment of medical expenses of participants will, to the extent enforceable under applicable laws, be the responsibility of eligible participants; settling defendants will have no additional responsibilities to such insurers and agencies and will be protected by participants against such claims.

* * *

R.12 Exhibit I

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In re: SILICONE GEL BREAST IMPLANT PRODUCTS LIABILITY LITIGATION (MDL 926)
Master File No. CV 92-P-10000-S,

HEIDI LINDSEY, et al., Plaintiffs;

-vs-

DOW CORNING CORPORATION, et al., Defendants
Civil Action No. CV 94-P-11558-S

BREAT IMPLANT LITIGATION NOTICE

* * *

26. **Incorporation of Terms of Global Settlement.** The revised settlement program implements paragraph 18 of the notice of the global settlement by reducing—for those eligible to participate—the extent of ratcheting that would otherwise occur and by preserving—for those not eligible to participate—their rights to opt out of the class (while providing an extension of the period during which statutes of limitation and repose would be suspended). Except to the extent modified by or inconsistent with the terms of this Notice, the settlement terms announced in the April 1994 notice (including, for example, provisions relating to contribution and indemnification claims against the settling defendants and released parties) remain in effect and govern

rights, obligations, and options. The benefits provided under the revised settlement supersede and are in lieu of all benefits that participants and their attorneys might have had under the global settlement. The Court retains general powers to administer and implement the settlement, including the power to interpret the terms of the settlement and to resolve on an equitable basis conflicting claims to benefits arising because of death of a participant or asserted assignments or liens relating to payment of benefits.

* * *

(3)

Supreme Court, U.S.
FILED
MAY 2 4 2004
OFFICE OF THE CLERK

No. 03-1341

In the Supreme Court of the United States

BAXTER INTERNATIONAL INC., ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

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QUESTIONS PRESENTED

The Medicare Secondary Payer (MSP) statute, 42 U.S.C. 1395y(b)(2), was amended after the court of appeals issued its decision in this case. The petition presents the following questions concerning the proper interpretation of the version of the MSP statute that was in effect at the time the court of appeals ruled:

1. Whether the court of appeals correctly held that the statutory term "self-insured plan" included entities that self-insure only in part, by purchasing excess insurance that is triggered after a liability threshold is met.

2. Whether the court of appeals correctly held that an entity could maintain a "self-insured plan" within the meaning of the MSP statute without establishing formal procedures by which funds were set aside and then could be drawn upon to cover claims.

3. Whether the court of appeals correctly held that petitioners could be held liable under the MSP statute as entities that "received payment" from products liability insurers that were responsible for reimbursing the Medicare program.

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In the Supreme Court of the United States

No. 03-1341

BAXTER INTERNATIONAL INC., ET AL., PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-70a) is reported at 345 F.3d 866. The opinion of the district court (Pet. App. 71a-108a) is reported at 174 F. Supp. 2d 1242.

JURISDICTION

The judgment of the court of appeals was entered on September 15, 2003. The petition for rehearing was denied on December 23, 2003 (Pet. App. 110a-112a). The petition for a writ of certiorari was filed on March 22, 2004. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. This action was brought by the United States pursuant to the Medicare Secondary Payer (MSP) statute, 42 U.S.C. 1395y(b)(2). In December 2003, after the court of appeals issued the decision that petitioners would have this Court review, Congress amended the MSP statute in a manner that largely codifies the interpretation given the statute by the Secretary of Health and Human Services and sustained by the court of appeals. Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 301, 117 Stat. 2221. Those amendments apply as if included in the MSP statute in 1980, and therefore will now govern the proceedings on remand. The following description refers to the version of the statute that was in effect at the time the court of appeals issued its decision.

The MSP statute was enacted in 1980 to reduce the Medicare program's rising costs. H.R. Rep. No. 1167, 96th Cong., 2d Sess. 352 (1980); *Zinman* v. *Shalala*, 67 F.3d 841, 843, 845 (9th Cir. 1995). The statute makes the Medicare program secondary to other plans that cover the costs that Medicare would otherwise absorb. The statute was designed to lower overall federal Medicare disbursements by requiring Medicare beneficiaries to exhaust all available insurance coverage before resorting to their Medicare coverage. *United States* v. *Rhode Island Insurers' Insolvency Fund*, 80 F.3d 616, 618 (1st Cir. 1996).

Toward that end, the MSP statute establishes two principal directives. First, it sets out the circumstances under which Medicare should withhold payment. If payment has been made by a "liability insurance policy or plan (including a self-insured plan) or under no fault

insurance" for the same medical care, or if such payment can reasonably be expected to be made "promptly," Medicare may not pay. 42 U.S.C. 1395y(b)(2)(A)(ii). That prohibition "is intended to keep the government from paying a medical bill where it is clear an insurance company will pay instead." *Evanston Hosp.* v. *Hauck*, 1 F.3d 540, 544 (7th Cir. 1993), cert. denied, 510 U.S. 1091 (1994).

Second, the statute sets out the circumstances under which Medicare must be reimbursed for the payments it does make. If Medicare cannot reasonably expect payment (or prompt payment) from another insurance plan, Medicare is authorized to pay. 42 U.S.C. 1395y(b)(2)(A)(ii). The statute specifies, however, that such Medicare payments are conditional and must be repaid to Medicare if another insurance plan's responsibility to pay is established. 42 U.S.C. 1395y(b)(2)(B)(i).

To further the goal of reducing Medicare costs, Congress defined broadly the kinds of insurance that are deemed primary to Medicare. The statutory definition of "primary plan" expressly includes liability insurance plans that are self- insured. 42 U.S.C. 1395y(b)(2)(A) ("the term 'primary plan' means * * * a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance").

If the Medicare program is not reimbursed for its payments as required under the MSP statute, the United States may bring suit to obtain reimbursement. The MSP statute authorizes the United States to bring an action against "any entity which is required or responsible * * * to make payment * * * under a primary plan" and against "any other entity (including any physician or provider) that has received payment from that entity." 42 U.S.C. 1395y(b)(2)(B)(ii).

The MSP statute also gives the United States a right of subrogation, in addition to the direct right of action just described. 42 U.S.C. 1395y(b)(2)(B)(iii). Under the subrogation provision, if an entity that should have reimbursed the Medicare program pays a different party (such as a tort victim) instead, that entity remains liable to the government as long as it knew or should have known of Medicare's conditional payment. *Health Ins. Ass'n of Am., Inc.* v. *Shalala*, 23 F.3d 412, 418 (D.C. Cir. 1994) (*HIAA*) ("If a third party payer wants to avoid having to make two payments for the same service, it should refrain from paying someone whom it knows or should know that [Medicare] already has paid."), cert. denied, 513 U.S. 1147 (1995); Pet. App. 55a-56a (following *HIAA* and observing that "the constructive knowledge standard is fully consistent with the intent of the MSP statute, and indeed necessary if the statute is to fulfill its purpose," because "the insurer that pays second is in the superior position to prevent an erroneous or misdirected payment").

2. a. This case arises out of the 1995 settlement of mass tort litigation against the manufacturers of breast implants. In 1994, the federal government informed the settling parties that, to the extent the government had made Medicare payments for the victims' implant-related medical care, the MSP statute required that Medicare be reimbursed. Pet. App. 3a. The 1995 settlement (known as the Revised Settlement Program, or RSP) established a mechanism by which breast implant recipients could obtain compensation from a fund created pursuant to the settlement. *Id.* at 152a-153a (Compl. ¶¶ 15-20). The RSP did not, however, provide for reimbursement of the federal government's Medicare payments, and the manufacturers made settlement payments or caused settlement payments to be made to

claimants from the settlement fund without regard to whether Medicare had paid their implant-related medical expenses. *Id.* at 156a-157a (Compl. ¶¶ 37-42); *id.* at 3a n.1. The manufacturers likewise made settlement payments to implant recipients who opted out of the settlement class, without regard to whether Medicare had paid for their implant-related expenses. *Id.* at 153a-154a, 157a (Compl. ¶¶ 20-22, 39-40).

Beginning in 1995 and continuing through March 2000, the United States entered into a series of tolling agreements with the manufacturers while it attempted to negotiate a resolution of its claims. Pet. App. 5a. After settlement discussions proved unsuccessful, the United States brought this action for monetary and injunctive relief under the MSP statute, naming as defendants the manufacturers that are petitioners here: Baxter International Inc.; Baxter Healthcare Corporation; Bristol-Myers Squibb Company; Minnesota Mining and Manufacturing Company; and Union Carbide Corporation.[1]

The complaint alleges that the United States, through the Medicare program, has paid for implant-related medical care on behalf of thousands of women, including women receiving compensation from the petitioners. Pet. App. 154a, 159a (Compl. ¶¶ 26, 55). The complaint in two respects seeks reimbursement from the petitioners for those Medicare payments (as well as prospective relief) under the MSP statute. First, the complaint alleges that petitioners were liable to the Medicare beneficiaries under a "primary plan" because they were "self-insured" (42 U.S.C. 1395y(b)(2) and (b)(2)(B)(ii)), at least in part, against the risk of

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[1] The complaint also named the settlement fund's escrow agent as a defendant. The escrow agent is not a petitioner here.

products liability claims by breast implant recipients. Pet. App. 157-158a, 160a-161a (Compl. ¶¶ 43-44, 58-59, 67-68). Second, the complaint alleges that petitioners alternatively or additionally were responsible for reimbursing the Medicare program as entities that "received payment" (42 U.S.C. 1395y(b)(2)(B)(ii)) from their products liability insurers with respect to implant-related claims. Pet. App. 158a, 161a (Compl. ¶¶ 45-46, 64-65).

b. The district court dismissed the complaint for failure to state a claim. Pet. App. 71a-108a. Although the court offered various grounds for its ruling, only two are relevant to the petition.

First, in dismissing the "self-insurance" counts, the court declared that the statutory term "self-insured plan" does not encompass entities that self-insure only in part, by purchasing excess insurance that is triggered after a liability threshold is met. Pet. App. 84a & n.12. The court opined, further, that a "self-insured plan" necessarily requires "some type of formal arrangement by which funds are set aside and accessed to cover future liabilities," *id.* at 84a, factors that the government had not specifically alleged in its complaint.

Second, the court concluded that petitioners could not be held liable as entities that "received payment" from another insurance plan responsible for reimbursing Medicare, notwithstanding petitioners' alleged receipt of the proceeds of their products liability insurance. In the court's view, petitioners must be regarded as mere "pass-through" entities between their own insurers and the implant recipients. Pet. App. 95a-100a.

c. A unanimous panel of the Eleventh Circuit reversed in relevant part, remanding the case for dis-

covery and other further proceedings. Pet. App. 1a-70a.

Addressing the district court's "self-insurance" rulings, the court rejected the conclusion that the statutory term "self-insured" could not apply to entities that self-insure only in part, by carrying their own risk up to a certain amount and procuring insurance policies to cover the excess. Pet. App. 42a-47a. The court observed that, to prevent responsible parties from eluding MSP liability, the Secretary's regulations defined the statutory term "self-insured" broadly as a plan under which an entity "carries its own risk instead of taking out insurance with a carrier." *Id.* at 45a (quoting 42 C.F.R. 411.50(b)). The court explained that there was "nothing in the plain meaning of the statute which might preclude the agency's interpretation to include within the self-insured concept the commonly occurring circumstances of an individual or entity planning ahead of time to assume responsibility and liability for certain risks up to a designated amount, and to procure an insurance policy to cover the excess." *Id.* at 47a. To the contrary, the court reasoned, while some authorities interpret the term "self-insured plan" rigidly, it "is interpreted by other authorities to include precisely such a combination of self-insurance up to a certain amount with the excess to be covered by an insurance policy." *Ibid.*; see, *e.g.*, *id.* at 48a n.23 (noting that the 1979 edition of *Black's Law Dictionary* (at 1220) explained, in defining self-insurance, that "[a] common practice of businesses is to self-insure up to a certain amount, and then to cover any excess with insurance").

The court of appeals similarly rejected the district court's conclusion that the term "self-insured plan" requires proof of a formal arrangement by which funds were set aside and providers were made to use them to

cover future liabilities. Pet. App. 42a-52a. The court noted that the agency's regulations define the term "plan" to include "any arrangement, oral or written, by one or more entities, to . . . assume legal liability for injury or illness," *id.* at 45a (quoting 42 C.F.R. 411.21), and that the inclusion of the term "oral" suggested "an intent to reach informal, ad hoc arrangements in addition to traditional insurance policies." *Ibid.* The court held that the agency's view was "especially persuasive in the absence of a universally accepted and authoritative definition of 'self-insured plan' which Congress might have contemplated in drafting the statute." *Ibid.*; see, *e.g.*, *id.* at 47a ("Even the sparse legal authority which suggests that there usually will be a reserve for losses, also indicates that 'self-insurance' has no precise legal meaning."). Although the court disagreed with *dicta* in the Fifth Circuit's decision in *Thompson* v. *Goetzmann*, 315 F.3d 457 (2002), opinion withdrawn and reissued as amended on other grounds, 337 F.3d 489 (5th Cir. 2003), suggesting that a formal set-aside of funds was required, the court "fully agree[d] with the Fifth Circuit that the term 'plan' in the statutory term 'self-insured plan' clearly contemplates an *ex ante* arrangement." Pet. App. 49a.

In its "received payment" ruling, the court of appeals remanded to allow the government an opportunity to prove that petitioners may be held liable, based on their alleged receipt of the proceeds of their products liability insurance policies, under the statutory provision allowing the government to recover from "any other entity (including any physician or provider) that has received payment" from any primary plan. Pet. App. 64a (quoting 42 U.S.C. 1395y(b)(2)(B)(ii)). The court explained that it could assume that "Congress intended the term 'any other entity' to be understood with reference to

'physician' and 'provider,' and to encompass only entities of like kind." *Id.* at 65a. The court further observed that, although the record is "devoid of detail about the role of [petitioners'] liability insurance carriers," it appears that petitioners "initially financed the settlement, then filed claims with their insurers, which will provide reimbursement based on their independent evaluation of the class members' claims." *Id.* at 68a. The court explained that, if so, the district court's description of petitioners as "mere intermediaries between their insurance companies and the class members is not accurate." *Ibid.* The court remanded to allow the government to develop evidence relevant to this aspect of the suit. *Id.* at 68a-69a.

d. The court of appeals denied the petitions for rehearing and rehearing en banc, no active judge having asked for a vote on the en banc petition. Pet. App. 111a-112a.

3. On December 8, 2003, after the panel issued its decision in this case, the President signed into law the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066. Section 301 of that Act amends the MSP provisions in a manner that largely codifies the interpretations of the Secretary of Health and Human Services on the issues raised by the petition. The title of Section 301(b) reflects that Congress regarded these amendments as "[c]larifying" the MSP statute. 117 Stat. 2221. Section 301(d) further provides that the amendments in Section 301(b) are effective as if included in the MSP statute as originally enacted in 1980. 117 Stat. 2222.

As particularly relevant here, Section 301(b)(1) provides that "[a]n entity that engages in a business, trade, or profession shall be deemed to have a self-

insured plan if it carries its own risk (*whether by failure to obtain insurance, or otherwise*) *in whole or in part.* 117 Stat. 2222 (emphases added). That provision accordingly makes clear that the existence of a self-insured plan does not depend upon a formal set aside of funds or formal claims procedures, and that an entity that has procured liability insurance may nonetheless be considered to be self-insured for any amount for which the entity carries its own risk.

Additionally, Section 301(b)(3) of the 2003 Act also deletes the parenthetical phrase "including any physician or provider" from the "received payment" provision of the MSP statute, and provides that "the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity." 117 Stat. 2222; accord *ibid.* (Section 301(b)(2) amends the MSP statute to provide that "[a] primary plan, and an entity that receives payment from a primary plan, shall reimburse" the Medicare program for the payments it has made). Those amendments leave no doubt that the Secretary has a cause of action to seek reimbursement from entities such as petitioners that are alleged to have received payment from a primary plan, including a traditional liability insurance plan.

ARGUMENT

The interlocutory decision of the court of appeals interpreting the prior version of the MSP statute is correct and does not squarely conflict with the decision of this Court or of another court of appeals. To the extent that there is tension between the decision below and *dicta* from other courts of appeals concerning that prior version, the issues have been resolved by the

December 2003 amendments to the Medicare Secondary Payer statute. Accordingly, the petition for writ of certiorari should be denied.

1. Petitioners do not dispute that the 2003 amendments confirm the positions of the Secretary on the questions raised by the petition and that those amendments—not the provisions in effect when the court of appeals decided the case—will now govern the further proceedings in this case. Moreover, petitioners expressly do not present a constitutional challenge to the 2003 amendments (see Pet. 29). The petition nonetheless seeks review of the court of appeals' interpretation of prior law because petitioners assert that the law of the case doctrine will bar them from later raising a constitutional challenge to the amendments. Pet. 29-30. The court of appeals' decision, however, is purely interlocutory, and nothing would prevent petitioners from raising in this Court any issue—including a constitutional challenge and any issue concerning the prior law that might be relevant to such a challenge—after the entry of final judgment. There is, moreover, no reason at the present time to conclude that the questions petitioners seek to raise now will warrant the Court's review even after entry of a final judgment —assuming that petitioners are found liable in proceedings on remand, that they raise a constitutional challenge to their liability under the 2003 amendments in these proceedings, and that an interpretation of propr law appears relevant to their challenge at that time. Congress has expressed its view that the 2003 amendments clarify, rather than change, the MSP statute. Pub. L. No. 108-173, § 301(b), 117 Stat. 2221 (title describes the provisions in Section 301(b) as "Clarifying Amendments To Conditional Payment Provisions"). Such a congressional declaration about the

meaning of an earlier statute is itself given great weight. *Loving* v. *United States*, 517 U.S. 748, 770 (1996) ("[s]ubsequent legislation declaring the intent of an earlier statute is entitled to great weight") (quoting *Consumer Prod. Safety Comm'n* v. *GTE Sylvania, Inc.*, 447 U.S. 102, 118 n.13 (1969), and *Red Lion Broad. Co.* v. *FCC*, 395 U.S. 367, 380-381 (1969)). Moreover, if the Court concluded that review were warranted at that time, it would have the benefit of a more fully developed factual record, and would be able to consider the constitutional challenge in that context.

In any event, petitioners are manifestly incorrect in arguing (Pet. 26) that the 2003 amendments have "unsettled the expectations" of parties who either receive or make a payment relating to medical expenses for which the Secretary has previously made payment under Medicare. Petitioners do not (and cannot) dispute that the payment of products liability insurance proceeds on the basis of implant-related claims is precisely the sort of insurance coverage that triggers the MSP statute's obligation to reimburse Medicare. To the contrary, petitioners' contention in this litigation has largely been that the government may proceed only against the implant recipients. Cf. Pet. App. 52a n.28 (declining to address the argument that the government must attempt to recover from the class members before it may seek reimbursement from the manufacturers).

Petitioners' contention that the 2003 amendments unconstitutionally upset their own settled expectations is also incorrect. The government put petitioners on notice in 1994 (before they entered into the RSP) that, to the extent the government had made Medicare payments for the victims' implant-related medical care, reimbursement was required under the MSP statute.

Petitioners nonetheless thereafter chose at their own risk to make or direct settlement payments to implant recipients without regard to whether Medicare had paid for their medical care.

2. Petitioners argue (Pet. 17-22) that they cannot be regarded as maintaining self-insured plans because they are alleged to have conventional liability insurance for amounts in excess of those for which they carry their own risk. The court of appeals correctly rejected petitioners' contention that they cannot be regarded as having "self-insured" plans within the meaning of the MSP statute unless they carry their *entire* risk. As the court of appeals explained, ample authority supports the agency's interpretation that an entity may combine "self-insurance up to a certain amount with the excess to be covered by an insurance policy." Pet. App. 47a; see also *Black's Law Dictionary* 1220 (5th ed. 1979) ("A common practice of businesses is to self-insure up to a certain amount, and then to cover any excess with insurance.").

Contrary to petitioners' assertion (Pet. 15), the court of appeals' decision does not conflict with the Second Circuit's decision in *Mason* v. *American Tobacco Co.*, 346 F.3d 36 (2003), cert. denied, No. 03-1270 (May 17, 2004), or the Fifth Circuit's amended decision in *Thompson* v. *Goetzmann*, 337 F.3d 489 (2003). As the court of appeals observed, there was no suggestion in *Mason* that the tortfeasor had purchased any insurance. Pet. App. 46a n.22. Nor was there any such indication in *Goetzmann*, as petitioners acknowledge. See Pet. 17 ("The record in *Goetzmann* demonstrated that Zimmer had elected not to purchase product liability insurance[.]").

In any event, the December 2003 amendments to the MSP statute leave no doubt that a business entity shall

be deemed to have a "self-insured plan" if it carries its own risk "in whole or *in part*." Pub. L. No. 108-173, § 301(b)(1), 117 Stat. 2222 (emphasis added). Congress has thus resolved the issue that petitioners ask this Court to decide.

3. Petitioners also argue (Pet. 17-22) that they cannot be understood to have a "self-insured plan" within the meaning of the MSP statute unless they have formal procedures by which funds are set aside and then subject to claims to cover future liabilities. As the court of appeals explained, however, the Secretary has interpreted the statutory term "self-insured plan" broadly to include oral and other informal arrangements to assume liability. Pet. App. 45a; 42 C.F.R. 411.21. To be sure, under the Secretary's regulation interpreting the prior version of the MSP statute, "the mere absence of insurance purchased from a carrier does not necessarily constitute a 'plan' of self-insurance." 54 Fed. Reg. 41,727 (1989). As the court of appeals observed, both the statute and the regulation contemplate some form of "*ex ante* arrangement," and a tortfeasor's discrete settlement payment in a particular case does not by itself establish that it has a self-insured plan. Pet. App. 49a. As the court of appeals further explained, however, neither the statute nor the regulation imposes the additional requirement of a set-aside of funds or other formal procedures. *Id.* at 47a-48a; cf. 29 U.S.C. 1081(a)(1) (exempting welfare benefit plans from ERISA's funding requirements).

Although there are *dicta* in *Goetzmann* suggesting that a formal set-aside of funds is required, any tension between that decision and the decision below does not warrant this Court's review, particularly in light of the December 2003 amendments. As amended, the MSP statute provides that "[a]n entity that engages in a

business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (*whether by failure to obtain insurance, or otherwise*) in whole or in part. Pub. L. No. 108-173, § 301(b)(1), 117 Stat. 2222 (emphasis added). The amendment thus makes clear that no set-aside of funds or formal mechanism for payment of claims is required.

Moreover, the holding of *Goetzmann* is narrow. As the court of appeals in this case explained (Pet. App. 49a & n.24), the Fifth Circuit perceived the government's complaint in *Goetzmann* to allege that the tortfeasor was self-insured merely by virtue of its payment in settlement of a single tort claim. See, *e.g.*, *Goetzmann*, 337 F.3d at 495 ("In this case, the 'self-insurance plan' is alleged by the government to exist by virtue of Zimmer's payment to Medicare recipient Loftin under the terms of their products-liability settlement agreement."). *Goetzmann* thus stands for the unremarkable proposition that "an alleged tortfeasor who settles with a plaintiff is not, *ipso facto*, a 'self-insurer' under the MSP statute." *Id.* at 497.[2] The court of appeals in this case "fully agree[d]" with that aspect of the Fifth Circuit's decision. Pet. App. 49a.

In *Mason*, the Second Circuit expressly distinguished the court of appeals' decision in this case. 346 F.3d at 41-42. *Mason* was a private suit under the MSP statute; the government was not a party. The Second Circuit stressed that the private plaintiffs in *Mason* had

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[2] The government's rehearing petition in *Goetzmann* explained that the panel had misunderstood the government's argument. Pet. for Reh'g En Banc at 14-15, *Thompson* v. *Goetzmann*, 337 F.3d 489 (5th Cir. 2003) (No. 02-10198); Pet. for Panel Reh'g at 1, 12-13, *Goetzmann*, *supra* (No. 02-10198). The panel nonetheless chose to reissue the self-insurance portion of its decision unchanged.

not even established that the defendants were responsible to pay for anyone's medical care. *Id.* at 42. The court explained that, by contrast, the RSP settlement in this case left no doubt about the breast implant manufacturers' responsibility to pay. *Ibid.*

4. Petitioners also argue that they cannot be held liable based on their alleged receipt of payments under product liability insurance plans because they are simply pass-through entities who received payment under a primary plan. Pet. 22-25. The court of appeals assumed, however, that mere "pass-through" payers would not be covered by the MSP statute. Pet. App. 65a. Indeed, the court of appeals affirmed the district court's judgment insofar as it dismissed the damages count against the escrow agent who administers settlement funds, observing that the "uncontested evidence is that the Escrow Agent acts in a purely ministerial role serving the district court." *Ibid.*

By contrast, however, the court observed that the district court's characterization of petitioners as "mere intermediaries" might well prove inaccurate, with the benefit of discovery. Pet. App. 68a. That interlocutory ruling does not warrant this Court's review. Although petitioners allege a conflict with the D.C. Circuit's *HIAA* decision, *HIAA* merely held that a third-party administrator of an employer group health plan could not be held liable based on its receipt of payment from the plan. 23 F.3d at 415-417. The *HIAA* decision has no bearing on the government's claims against petitioners, whose right to the proceeds of their insurance policies cannot plausibly be equated with a third-party administrator's temporary possession of funds intended to pay liabilities for which the administrator has no personal liability. Petitioners would have received any of the funds at issue in their capacities as *insureds*

under policies that were intended to cover the very sort of injuries that led to Medicare payments, and would have received them precisely because of their responsibility for the injuries to the victims. Petitioners are not mere intermediaries, or like a bank that is clearing a check.

Moreover, the December 2003 amendments delete the parenthetical phrase "including any physician or provider," and thus make clear that there is no basis for narrowly interpreting the category of entities liable to reimburse Medicare when they receive payment from their liability insurance carriers. Pub. L. No. 108-173, § 301(b)(3), 117 Stat. 2222 (the federal government may recover "from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity"); Pub. L. No. 108-173, § 301(b)(2), 117 Stat. 2222 ("[a] primary plan, and an entity that receives payment from a primary plan, shall reimburse" the Medicare program for the payments it has made). The government is accordingly entitled to the proceeds allegedly received by petitioners under any primary plan which unquestionably includes a product liability insurance plan. 42 U.S.C. 1395y(b)(2).

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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In the Supreme Court of the United States

BAXTER INTERNATIONAL INC., BAXTER HEALTHCARE CORPORATION, BRISTOL-MYERS SQUIBB COMPANY, MINNESOTA MINING AND MANUFACTURING COMPANY AND UNION CARBIDE CORPORATION,

PETITIONERS,

v.

UNITED STATES OF AMERICA,

RESPONDENT.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

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ARGUMENT

1. The Government's attempt to characterize the decision below as creating mere "tension" with "dicta" from other circuits fails. Petitioners would have prevailed under the legal standards adopted in other circuits.

The Fifth Circuit. As explained in detail in the petition at 17-19, *Thompson v. Goetzmann*, 337 F.3d 489 (5th Cir. 2003), dismissed the Government's MSP complaint against a product manufacturer that settled a claim with a Medicare beneficiary for failure to allege facts sufficient to satisfy the definition of a "primary plan" under the MSP. *See also* Opp. at 15. The Court explained in unequivocal terms that "in the sense used in the MSP statute, a 'primary plan' of 'self-insurance' requires an entity's *ex ante* adoption, for itself, of an arrangement for (1) a source of funds and (2) procedures for disbursing these funds when claims are made against the entity." 337 F.3d at 498. The Government's complaint in this case similarly fails to allege any facts that would satisfy this definition of a "primary plan." Indeed, the Fifth Circuit cited the district court decision dismissing the Government's complaint *in this case* with approval. *Id.* at 499 n.26.

Instead of conceding this obvious conflict, the Government first asserts that *Goetzmann* is inapposite because the settling manufacturer had not purchased any product liability insurance whereas Petitioners did. Opp. at 16. The Government fails to explain why this factual distinction could possibly matter. If a manufacturer that purchases *no* coverage is not "self-insured" under the Fifth Circuit's interpretation of the MSP then surely a manufacturer that purchases insurance is not "self-insured."

The Government next contends there is no conflict because the Fifth Circuit merely held that "'an alleged tortfeasor who settles with a plaintiff is not, *ipso facto*, a "self insurer."'" Opp. at 15 (quoting 337 F.3d at 497). That circumscribed reading of the opinion is unpersuasive. The Fifth Circuit clearly held that any attempt to amend the allegations of self-insurance would be futile. *See* Pet. at 18

n.15. It explained that "[t]he term 'primary plan' is pivotal to the applicability of the MSP statute" (337 F.3d at 497); the definition of that term, when applied to self-insured plans, requires the advance creation of a fund to cover anticipated liabilities and procedures for disbursement (*id.* at 498); and the Government never contended in *Goetzmann* (or here) that it could allege those "pivotal" facts.

The Second Circuit. The Second Circuit also upheld the dismissal of an MSP complaint against product manufacturers for failure to allege facts sufficient to establish that they maintained self-insured plans within the meaning of the MSP. Like the Fifth Circuit in *Goetzmann*, the Second Circuit expressly adopted a definition of self-insured plan that requires that the settling tortfeasor acted as an insurance carrier for itself by creating a fund and disbursement procedures for future liabilities. *Mason v. United Tobacco Co.*, 346 F.3d 36, 41 (2d Cir. 2003), *cert. denied*, 72 U.S.L.W. 3712 (U.S. May 17, 2004).

The Government contends that *Mason* can somehow be reconciled with the decision below because "there was no suggestion in *Mason* that the tortfeasor had purchased any insurance." Opp. at 13. The Court's reasoning, however, reveals that it would be even less likely to find that tortfeasors that purchase insurance are self-insured. The Court emphasized that the "'logical implication'" of a definition of a self-insured plan that did not require a set aside of funds was that any entity "'with a risk of legal liability which chooses to retain any portion of that risk, no matter how small, may be pursued under MSP on the ground that it is a "self-insured plan."'" *Mason*, 346 F.3d at 40 (quoting *United States v. Philip Morris Inc.*, 156 F. Supp. 2d 1, 7 (D.D.C. 2001)). Nor can *Mason* be distinguished on the theory that "the RSP settlement in this case left no doubt about the breast implant manufacturers' responsibility to pay." Opp. at 16. The Court's observation that the RSP Defendants had "assumed obligations to pay" was based upon a misunderstanding of the record here. As

the Second Circuit understood, the MSP predicates liability on a showing that the defendant is "required or responsible . . . to make payment . . . *under a primary plan.*" 42 U.S.C. § 1395y(b)(2)(B)(iii) (emphasis added). What the Second Circuit obviously did not know is that the Government disavowed any claim that the RSP was a "primary plan" (Pet. at 19-20 n.16). Thus, the fact that Petitioners assumed a "responsibility to pay" under "the RSP settlement" (Opp. at 16), is of no legal consequence because the RSP is not a "primary plan."

The D.C. Circuit. The Eleventh Circuit's analysis of Petitioners' potential liability as entities that "received payment" cannot be reconciled with *HIAA*, where the D.C. Circuit squarely held that Congress required the Government to sue the *insurer* and not a pass-through payer, except in limited circumstances. *Health Ins. Ass'n of Am., Inc. v. Shalala*, 23 F.3d 412, 416-17 (D.C. Cir. 1994) ("*HIAA*"), *cert. denied*, 513 U.S. 1147 (1995). As explained in the Petition at 24, the Eleventh Circuit reasoned that *HIAA* was distinguishable based upon the mistaken premise that the third-party administrator would have no involvement in any decision to make a payment to a claimant. The Government makes no effort to defend this reasoning. It instead asserts that *HIAA* has "no bearing" on the issue here because Petitioners, unlike the third-party administrator in *HIAA*, have "personal liability" to the claimants under the RSP. Opp. at 16. The operative legal issue in *HIAA*, however, is whether the party handling the primary payment "assume[d] financial responsibility for paying a plan's benefits." 23 F.3d at 416. Nothing in the Government's complaint does or could allege that Petitioners assumed financial responsibility for making liability insurance payments. The D.C. Circuit's analysis accordingly leaves no doubt that it would not permit the Government to bypass the insurer and "proceed directly against [settling tortfeasors]." *Id.* at 417.

2. The Eleventh Circuit acknowledged that many authorities have defined "self-insured" plans to refer to a formal arrangement by which funds are set aside and accessed to cover future liabilities. Pet. App. at 43a. It nevertheless held that this definition—which had been adopted by every other court to consider the issue—was not dispositive because courts are required to "look to the regulations to which we owe deference," *id.* at 51a, and it read CMS regulations *sua sponte* to define "deductibles" as a form of self-insurance. *Id.* at 45a, 47a. The Eleventh Circuit accordingly concluded that a "combination of deductibles and insurance policies" may be "deemed by the regulations to constitute a self-insured plan" even if that definition of self-insurance departs from the customary meaning of the term. *Id.* at 51a-52a. The Government avoids any effort to defend this reasoning. As it undoubtedly knows, the agency's own regulations provide no support for this conclusion.

First, the Government never acknowledges that the Eleventh Circuit held that the purchase of a policy with "deductibles" can constitute a plan of self-insurance. It instead describes the issue as whether an entity could be self-insured in part by "purchasing excess insurance that is triggered after a liability threshold is met." Opp. at (I). But the complaint does not allege and the Eleventh Circuit does not base its ruling on the purchase of "excess insurance policies."[1] The Eleventh Circuit instead interprets the Government's allegations to be that Petitioners purchased insurance policies with deductibles, and bases its legal holding on that premise. *See* Pet. App. at 42a n.19, 47a, 51a.

Second, the Government offers no response to Petitioners' showing (Pet. at 20-22) that the Eleventh

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[1] "Excess Insurance" refers to "a form of additional protection ... purchased by the insured ... which by its terms will only come into play once the limits of the primary policy have been exhausted." 1 Eric Mills Holmes & Mark S. Rhodes, *Holmes's Appleman on Insurance* § 2.16, at 323 (2d ed. 1996).

Circuit completely misunderstood the meaning of the regulation that defines a "deductible" as a "liability insurance payment." The Government's silence can only be understood as a concession that the regulation *does not define deductible payments as a form of self-insurance.* Yet this "deductible" regulation was the centerpiece of the Eleventh Circuit's rejection of *Goetzmann*'s interpretation of a self-insured plan. Pet. App. at 45a, 47a, 51a.

Third, CMS has *required* a set aside of funds to qualify as a self-insured plan in a related context and squarely rejected the view that a deductible is a form of "self insurance." Under both Parts A and B of the Medicare laws, CMS reimburses certain costs incurred by health care providers (42 U.S.C. § 1395x(v)), including contributions made to a "self-insurance program" to cover future liabilities. 42 C.F.R. § 413.100(c)(2)(viii). These CMS regulations recognize that self-insurance "is a means by which a provider . . . undertakes the risk of protecting itself against anticipated liabilities *by providing funds in an amount equal to anticipated liabilities*, rather than by purchasing insurance coverage." *Id.* § 413.100(b)(2) (emphasis added). And the CMS Medicare Provider Reimbursement Manual requires *an advance set-aside of funds* with a "recognized independent fiduciary" to qualify as a "self-insurance program." CMS Pub. 15-1 § 2162.7(B) (http://www.cms.hhs.gov/manuals/pub151/PUB_15_1.asp).

The Manual also confirms that an insurance policy with a deductible would not constitute partial self-insurance due to the absence of a set-aside. *Id.* §§ 1262.4, 2162.7(B)(2) (requiring a fiduciary who, *inter alia*, "must have legal title to the fund and be responsible for proper administration and control"). The fact that the agency has adopted the customary definition of self-insurance when it is footing the bill for the costs of a self-insured plan directly undermines the Eleventh Circuit's view that the regulations *required* it to depart from the ordinary meaning of the term "self-insured plan."

Finally, the Government makes no effort to support the Eleventh Circuit's conclusion that Petitioners may have "received payment" under the MSP because they are "private insurers" within the meaning of CMS regulations. Pet. App. at 68a-69a & n.40 (quoting 42 C.F.R. § 411.24(g)). The Government simply ignores the Eleventh Circuit's reasoning and asserts that Petitioners are liable because they "received payment" in their capacity as "insureds." Opp. at 16-17. As the Eleventh Circuit implicitly recognized, that conclusion is not supported by the regulations which set forth a long list of the parties potentially responsible as entities that "received payment." And the terms "insured" or "tortfeasor" appear nowhere on the list. 42 C.F.R. § 411.24(g). That omission makes perfect sense because an insured tortfeasor—unlike the parties identified in the regulation—does not receive insurance proceeds pursuant to rights based in subrogation.[2] *See* Pet. at 24-25. Thus, the Government's litigating position is again divorced from the text of the agency's own regulations.

3. The Government asserts that review of the questions presented in the petition is no longer necessary because "the issues have been resolved by the December 2003 amendments to the Medicare Secondary Payer statute." Opp. at 10-11. To begin with, the 2003 amendments only amend the definition of a self-insured plan for an "entity that engages in a business, trade, or profession." Opp. at 9-10. The divergent interpretations of "self-insured plan" adopted by the circuits will accordingly continue to govern the MSP liability of every individual tortfeasor who settles a claim with a Medicare beneficiary. In the Eleventh Circuit,

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[2] The sole exception is the beneficiary who has received the Medicare benefits from the Government on the condition that the Government is subrogated to the beneficiary's rights to recovery from other sources. *See Waters v. Farmers Tex. County Mut. Ins. Co.*, 9 F.3d 397, 400-01 (5th Cir. 1993) (the Government, whether pursuing its recovery pursuant to a direct cause of action under § 1395y(b)(2)(B)(ii) or a subrogation cause of action under § 1395y(b)(2)(B)(iii) "stands exactly in [the beneficiary's] shoes when recovering from the available insurance funds").

an individual who carries insurance with a deductible—but does not set aside funds in advance to cover anticipated liabilities and establish procedures for paying claims—will have obligations to the Government under the MSP. In the Second and Fifth Circuits, an individual in identical circumstances will have no liability to the Government.

Nor have "the issues . . . been resolved" for businesses. The Government does not deny that its interpretation of the MSP will impose liability on thousands of individuals and businesses who participated in settlements prior to the effective date of the amendments, as explained in the Petition at 26-28; that these individuals and entities *would not have been liable* under the definition of a self-insured plan adopted in the Fifth and Second Circuits; and that the threshold issue in a constitutional challenge to these retroactive changes in the MSP will necessarily be the correct interpretation of the provisions interpreted by the Eleventh Circuit in this case. *See* Pet. at 29-30. Thus it is crystal clear that the Eleventh Circuit's decision in this case will continue to control the issues on remand in this action despite the amendments.[3]

The Government tries to minimize the seriousness of these issues. It first asserts that "Congress has expressed its view that the 2003 amendments clarify, rather than change, the MSP statute" by including a title that describes the provisions in Section 301(b) as "Clarifying Amendments To Conditional Payment Provisions." Opp. at 11. Nothing in this Court's cases, however, suggests that the use of the term "clarifying" in the title of the amendments establishes

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[3] Some courts may reject the Government's reading of the amendments and decline to interpret the new law to "deem" that a business which insures future liability through the purchase of insurance policies with deductibles is maintaining any "self-insured plan." In order to reach that result, a court would have to interpret the meaning of the statute prior to the amendment. *See, e.g., Dep't of Commerce v. United States House of Representatives*, 525 U.S. 316, 341 (1999) (construing amendment narrowly in light of proper interpretation of statutory language prior to amendment).

that there has not been a retroactive change in the law. To the contrary, this Court has repeatedly declined to defer to the views of a subsequent Congress concerning the meaning of a statute adopted by a prior Congress.[4]

It takes little analysis to conclude that the amendments work a sea change in the law. For example, the amendment provides that any entity that fails to obtain insurance is "deemed" to have a "self-insured plan." MMA, Pub. L. No. 108-173, § 301(b)(1), 117 Stat. 2066, 2222 (2003). In 1989, CMS interpreted the pre-amendment version of the MSP quite differently, concluding that "the mere absence of insurance purchased from a carrier does not necessarily constitute a 'plan' of self-insurance." 54 Fed. Reg. 41,716, 41,727 (Oct. 11, 1989). The Eleventh Circuit, the Fifth Circuit, and the Second Circuit all have held, citing the 1989 CMS ruling, that the mere failure to purchase insurance does not mean an alleged tortfeasor is self-insured. *United States v. Baxter Int'l, Inc.*, 345 F.3d 866, 894, 895-96 (11th Cir. 2003); *Goetzmann*, 337 F.3d at 497 n.33; *Mason*, 346 F.3d at 41. Yet the 2003 amendment changes the law so that all entities that fail to obtain insurance *are* necessarily self-insured.

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[4] *See O'Gilvie v. United States*, 519 U.S. 79, 90 (1996) ("[T]he view of a later Congress cannot control the interpretation of an earlier enacted statute."); *Mackey v. Lanier Collection Agency & Serv., Inc.*, 486 U.S. 825, 839 (1988) (applying same principle even where Congress seeks to clarify earlier law's "original meaning"; *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 520 (1992) (same). The cases cited by the Government (Opp. at 12) are not to the contrary. *See Loving v. United States*, 517 U.S. 748, 770 (1996) (holding that the meaning of the statute was confirmed by other statutes); *Consumer Prod. Safety Comm'n v. GTE Sylvania, Inc.*, 447 U.S. 102, 117-18 & n.13 (1980) (refusing to hold that "subsequent legislation declaring the intent of an earlier statute is entitled to great weight," and resting its holding upon the canon that "the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one"); *Red Lion Broad. Co. v. FCC*, 395 U.S. 367, 380-81, 382-83 (1969) (relying on additional considerations to interpret the earlier statute that are inapposite here, including the fact that a contrary interpretation would have rendered it meaningless).

The Government further suggests that a constitutional challenge to the retroactive imposition of liability on Petitioners would not succeed because "[t]he government put petitioners on notice in 1994 . . . that . . . reimbursement was required under the MSP statute" (Opp. at 12) but "[t]he RSP did not . . . provide for reimbursement of the federal government's Medicare payments." Opp. at 4. That characterization ignores the record. As explained in the Petition at 4-6, Judge Pointer ensured that the RSP was administered in a manner that would provide for reimbursement to Medicare and other insurers by permitting the interception of benefits once the Claims Office determined who was eligible for payments from the fund. Other insurers, including state agencies, received reimbursement in this manner, but the Government never sought recovery. Thus, Petitioners reasonably believed that the interests of the United States were fully protected by the terms of the settlement structure adopted by Judge Pointer and there was nothing in the text of the MSP or the Government's implementing regulations that purported to impose liability on a settling tortfeasor. A retroactive change in the law would accordingly work a fundamental impairment of Petitioners' rights.

4. The Government requests this Court to deny the petition because the decision below is interlocutory and remand proceedings will result in a further development of the record. Opp. at 11-12. Both propositions are true, but neither support the conclusion that review of the issues presented would be premature. To the contrary, the issues here are questions of law that do not depend on the facts, and this Court has long recognized its authority to resolve interlocutory issues that are "fundamental to the further conduct of the case." *United States v. Gen. Motors Corp.*, 323 U.S. 373, 377 (1945); *see also Gillespie v. United States Steel Corp.*, 379 U.S. 148, 152-54 (1964) (interlocutory review warranted where "the eventual costs, as all the parties recognize, will certainly be less if we now pass on the

questions presented here rather than send the case back with those issues undecided").

As the decision of the Fifth and Second Circuits make plain, the "pivotal" question under the MSP at the time Petitioners settled the claims at issue—and the pivotal question even today for individual tortfeasors—is whether they can be liable as "self-insured plans" if they did not establish *ex ante* funds and procedures for covering anticipated future liabilities. In the Fifth and Second Circuits, complaints that did not allege such facts were dismissed as a matter of law; in the Eleventh Circuit those facts are irrelevant to proof of liability. Thus, if this Court resolves the conflict by approving the definition of self-insured plan adopted in the Fifth and Second Circuits, Petitioners will have refuted the Government's assertion that the MSP amendments merely serve as a "clarification" of the prior law and prevailed on an issue that they effectively concede is "fundamental to the further conduct of the case." *Gen. Motors*, 323 U.S. at 377; *see* Pet. at 26-30.

There is accordingly no question that "the eventual costs" to the litigants and the judicial system, *Gillespie*, 379 U.S. at 153, would be far greater if Petitioners are forced to proceed with voluminous discovery and years of litigation in a case that should have been dismissed on the basis of undisputed facts at the pleading stage. Moreover, the conflict on this issue will have to be resolved eventually because it continues to determine the rights and liabilities of thousands of individuals and entities who entered into settlements before the amendments and every individual tortfeasor who settles claims with Medicare beneficiaries after the effective date of the amendments. Postponing review accordingly serves no purpose and will merely breed confusion for years to come.

CONCLUSION

For the reasons set forth above, the petition for certiorari should be granted.

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IN THE

Supreme Court of the United States

BAXTER INTERNATIONAL INC., BAXTER HEALTHCARE CORPORATION, BRISTOL-MYERS SQUIBB COMPANY, MINNESOTA MINING AND MANUFACTURING COMPANY AND UNION CARBIDE CORPORATION,

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

On Petition For a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF ADVANCED MEDICAL TECHNOLOGY ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

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IN THE

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Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

On Petition For a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF OF ADVANCED MEDICAL TECHNOLOGY ASSOCIATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

INTEREST OF THE *AMICUS CURIAE*[1]

Advanced Medical Technology Association ("AdvaMed") is the largest medical technology association in the world, representing more than 1,200 medical device, diagnostic and

[1] Pursuant to Rule 37.6 of the Rules of this Court, *amicus* states that no counsel for a party has authored this brief in whole or in part, and that no person or entity, other than the *amicus*, its members, or its counsel, has made a monetary contribution to the preparation or submission of this brief.

health information system manufacturers.[2] AdvaMed's members manufacture 90 percent of the $75 billion of health care technology purchased annually in the United States and more than 50 percent of the $175 billion purchased around the world annually.

AdvaMed's members are innovators of technologies that save lives and increase the quality of life for hundreds of thousands of patients every year. For example, technological breakthroughs such as coronary stents, implantable defibrillators and minimally invasive bypass surgery have helped reduce the death rate from heart disease by 40 percent since 1980.

In addition, medical technology reduces procedure times, hospital stays and patient recovery times and enables many treatments to be shifted to less costly sites of care. Coronary stenting, an effective alternative to open heart bypass surgery, for example, costs one-half as much, takes one-half the time to conduct and reduces the hospital stay from five or six days to one day.

AdvaMed's members spend an enormous amount of money—roughly $9 billion annually—on research and development of these innovations. On a percentage of sales basis, this investment constitutes more than four times the average spent on research and development by manufacturers in other industries.

Although they have a large positive impact on the health of patients, medical technology companies are by no means all large corporations. In fact, 90 percent of these companies have 100 or fewer employees. *Technology, Innovation, and the Costs of Health Care: Hearing Before the Joint Econ. Comm.*, 108th Cong. (2003) (Testimony of Advanced Medical Technology Association).

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[2] AdvaMed was formerly the Health Industry Manufacturers Association ("HIMA").

One of the inevitable consequences of innovation in health care technology is that a small percentage of patients suffer injuries that they allege were caused by defective products. Thus, medical technology companies, like most other businesses, purchase liability insurance to cover the risks of these injuries. Like most purchasers of insurance, including both corporations and individuals, AdvaMed's members pay premiums to insurance companies for policies that require a certain deductible amount to be met before the insurance company begins paying on claims.

AdvaMed and its members have a significant interest in the outcome of this litigation. Nearly all of AdvaMed's members do now or will in the future face tort litigation concerning the medical devices they manufacture. The Eleventh Circuit's decision in this case would transform all of AdvaMed's members into "self-insured plans" with respect to that litigation with resulting liability under the Medicare Secondary Payer statute. This creates significant uncertainty for AdvaMed members who have chosen to settle such litigation in the past.

ARGUMENT

I. THE DECISION BELOW CONFLICTS WITH OTHER CIRCUITS' HOLDINGS AND WITH THE STATUTE'S LANGUAGE, HISTORY AND IMPLEMENTING REGULATIONS.

As its name suggests, the Medicare Secondary Payer statute ("MSP"), 42 U.S.C. § 1395y(b)(2), ensures that the Medicare program is not the primary insurer of a Medicare beneficiary's medical costs if there is a "primary plan" that also has responsibility to pay for those costs. During the period relevant to this case, the statute provided that, where the government paid Medicare funds to a beneficiary, it could seek reimbursement from an entity "which is required or responsible" to pay the beneficiary under a "primary plan" *or*

which has "received payment" from a "primary plan." *Id.* § 1395y(b)(2)(B)(ii).[3] "[P]rimary plan" is defined to include health plans, automobile or liability insurance plans and "self-insured plan[s]." *Id.* § 1395y(b)(2)(A). The statute does not define a "self-insured plan," but regulations promulgated by the Centers for Medicare and Medicaid Services ("CMS") define the term as "a plan under which an individual, or a private or governmental entity, carries its own risk *instead of taking out insurance with a carrier.*" 42 C.F.R. § 411.50(b)(2) (emphasis added). The government may recover double damages from a liable "primary plan." 42 U.S.C. § 1395y(b)(2)(B)(ii).

The Eleventh Circuit acknowledged that petitioners "had at least some liability [insurance] coverage," Pet. App. 5a—a fact that placed them outside the scope of the CMS definition of "self-insured plans." The lower court nevertheless concluded that the term "self-insured plan" should be interpreted to include petitioners because they had "plan[ned] ahead of time to assume responsibility and liability for certain risks up to a designated amount" by paying a deductible. *Id.* at 46a. The court rejected the view, adopted by the district court as well as the Fifth Circuit, that "self-insurance" requires a formal set-aside of funds to cover future liabilities. *Id.* at 46a-47a. Thus, under the Eleventh Circuit's holding, only those entities that carry liability insurance that is unlimited in coverage and scope would not be considered a "self-insured plan."

The court also held that because petitioners may have received reimbursement from their liability insurance carriers for a portion of the settlement amount, they had "received payment" from a "primary plan." Pet. App. 66a-67a. Accordingly, the government was entitled to seek both the funds that the petitioners paid into the settlement as part of

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[3] All references are to the MSP as it existed during the relevant time period.

the deductible portion of their liability insurance, as well as monies from petitioners' liability insurance companies that passed through petitioners and into the settlement fund.

The Eleventh Circuit's decision has created a sharp split of authority among the courts of appeals. The decision conflicts with the Second and Fifth Circuits' interpretation of a "self-insured plan," and with the District of Columbia Circuit's construction of the "received payment" prong of the MSP.

A. In *Thompson* v. *Goetzmann*, 337 F.3d 489 (5th Cir. 2003) (per curiam), the Fifth Circuit noted that six federal district courts and one bankruptcy court had already rejected the government's interpretation of the MSP to cover alleged tortfeasors who settle with injured plaintiffs—the same overly broad approach found in this case—as a "uniformly feckless" effort to expand the interpretation of the MSP. *Id.* at 503, 494. The *Goetzmann* court determined that a company's negotiation of a settlement with a litigant does not represent a "self-insurance" plan. See *id.* at 498. Instead, a corporation that acts as a "self-insured plan" would maintain a fund and establish disbursement rules like any other insurance carrier. See *id.* at 498-99.

Similarly, in *Mason* v. *American Tobacco Co.*, 346 F.3d 36, 40 (2d Cir. 2003), *cert. denied*, 72 U.S.L.W. 3580 (May 17, 2004) (No. 03-1270), the Second Circuit rejected the argument that a company that has not established a separate fund for its legal liabilities under a formal plan can nevertheless qualify as a "self-insured plan" if it "'retain[s] any portion of that risk, no matter how small.'" *Id.* at 40-41. Like the district court below, the Second Circuit concluded that the MSP was not the appropriate procedural vehicle to sue insured tortfeasors and dismissed the government's misguided attempt to categorize the defendant companies as self-insured plans. *Id.*

In the decision below, the Eleventh Circuit acknowledged its disagreement with the Fifth Circuit's conclusion in

Goetzmann that a self-insured plan involves a set-aside of funds to pay future liabilities and defines disbursement rules. See Pet. App. 49a. It attempted to dismiss that conclusion, however, as "dicta." *Id.* But, as petitioners have demonstrated, Pet. 18, the Fifth Circuit's construction of the term "self-insured plan" was essential to its judgment. The Third Circuit has recognized, moreover, that the Eleventh Circuit's definition of a "self-insured plan" creates a circuit split with the Fifth Circuit on this issue. See *Fanning* v. *United States*, 346 F.3d 386, 400 n.13 (3d Cir. 2003) ("[W]e note that the government's argument that a 'self-insured plan' includes a fund created by a tortfeasor to settle litigation has engendered a circuit split."), *petition for cert. filed*, 72 U.S.L.W. 3616 (Mar. 15, 2004) (No. 03-1327).

B. The Eleventh Circuit's decision also departs from the D.C. Circuit's conclusion in *Health Insurance Ass'n of America, Inc.* v. *Shalala*, 23 F.3d 412 (D.C. Cir. 1994), that the MSP does not impose liability on an entity that acts as a conduit for transferring insurance payments. The D.C. Circuit disagreed with the government's argument that the MSP permitted recovery actions against third-party administrators that issued payments on behalf of an insurer. See *id.* at 416-17. Instead, the D.C. Circuit held that the government should pursue not the administrators but, rather, the insurer. *Id.* Squarely contradicting the D.C. Circuit's well-reasoned analysis, the Eleventh Circuit found that the government could sue the insured tortfeasors who pass through insurance payments to the final recipients of the payment. See Pet. App. 66a-67a.

C. As the analysis of the Second, Fifth and D.C. Circuits confirms, the decision below is plainly wrong. By its terms, the MSP allows recovery from a "'primary plan' [which] means a group health plan or large group health plan . . . and a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance." 42 U.S.C. § 1395y(b)(2)(A). It

is well recognized that, "when a general word or phrase follows a list of specific persons or things, the general word or phrase will be interpreted to include only persons or things of the same type as those listed." *United States* v. *Ryan-Webster*, 353 F.3d 353, 365 (4th Cir. 2003). The district court in the *Mason* case followed that principle and recognized what the Eleventh Circuit did not.

> The list of responsible entities . . . primarily includes various types of insurance companies . . . . The logical inference is that a "self-insured plan" as included in that list means an entity that has assumed a posture similar to that of an insurance company. Defendants are not insurance companies and they have no apparent agreement or policy to be self-insured plans covering general tort claims.

Mason v. *American Tobacco Co.*, 212 F. Supp. 2d 88, 91 (E.D.N.Y. 2002) (citations omitted), *aff'd*, 346 F.3d 36 (2d Cir. 2003).

In addition, because the MSP provides for double damages, it is a penalty statute. It is of course well settled that "the law favors the narrow construction of penalty statutes." *In re Tax Refund Litig.*, 766 F. Supp. 1248, 1257 (E.D.N.Y. 1991), *aff'd in part, rev'd in part on other grounds*, *In re MDL-731 Tax Refund Litig.*, 989 F.2d 1290 (2d Cir. 1993); see also *Commissioner* v. *Acker*, 361 U.S. 87, 91 (1959). Yet the Eleventh Circuit adopted a breathtakingly expansive interpretation that treats as "self-insured" every tortfeasor whose insurance policy includes a deductible. See *infra* at 9-12.

Nothing in the MSP's legislative history supports this sweeping construction; to the contrary, it is clear that Congress did not intend the term "self-insured plan" to subject all insured tortfeasors whose policies include deductibles to double damages. Congress added the provision now in dispute to the Medicare statute in 1980. See Pub. L.

No. 96-499, tit. IX, § 953, 94 Stat. 2609, 2647 (1980). The language originated in the House and was designed to conserve Medicare funds in cases of automobile accidents where medical "services could have been paid for by a *private insurance carrier*." H.R. Rep. No. 96-1167, at 389 (1980), *reprinted in* 1980 U.S.C.C.A.N. 5526, 5752 (emphasis added). The Senate amendment reflected a similar concern and referred to situations in which "[M]edicare would be the secondary payer in any case where care can be paid for under any liability insurance policy (including an automobile insurance policy)." H.R. Conf. Rep. No. 96-1479, at 133 (1980), *reprinted in* 1980 U.S.C.C.A.N. 5903, 5924. In conference, the House and Senate agreed to include, as a subset of liability insurance, those arrangements defined as "self-insured" plans. *Id.*

In amendments to the MSP in 1989, neither House nor Senate indicated any intent to reach all tortfeasors. Congress confirmed that Medicare could recover costs "from *the liability insurer* of the person who caused the injury" under the MSP in cases involving liability insurance. H.R. Conf. Rep. No. 101-386, at 818-19 (1989), *reprinted in* 1989 U.S.C.C.A.N. 3018, 3421-22 (emphasis added). In 1995, Congress again noted in conference that the MSP program "identif[ies] situations where another *health care plan* should be . . . the primary payer." H.R. Rep. No. 104-87(I), at 4 (1995) (emphasis added). Thus, "the statute's clear purpose was to grant the Government a right to recover Medicare costs from insurance entities," *United States* v. *Philip Morris Inc.*, 116 F. Supp. 2d 131, 146 n.22 (D.D.C. 2000), and its "legislative history . . . provides no indication of a Congressional design to include an enormous group of potential tortfeasors as primary payors subject to double recovery under the statute." *Mason*, 212 F. Supp. 2d at 93.

Finally, Congress clearly knows how to impose reimbursement liability on tortfeasors. The Medical Care Recovery Act permits the government to collect from

tortfeasors—whether insured, uninsured or self-insured—the reasonable value of certain medical care provided to or paid for by the United States. See 42 U.S.C. § 2651(a). Congress, however, failed to include tortfeasors in the MSP, so it is utterly implausible to assume that Congress intended the term "self-insured plan" to confer a right to recover reimbursement of Medicare payments from all tortfeasors whose insurance policies include deductibles.

II. ALL TORTFEASORS, WHETHER INSURED OR UNINSURED, ARE SUBJECT TO MSP LIABILITY UNDER THE ELEVENTH CIRCUIT'S HOLDING.

The lower court's holding brings most, if not all, of AdvaMed's members—and virtually every business and individual in the nation—within the scope of the definition of a "self-insured plan" and renders them responsible for Medicare costs as a "primary plan." AdvaMed's members, like most businesses and individuals, protect against future losses by purchasing insurance. The insurance coverage purchased protects the insured from a specified amount or percentage of those losses, but insurance rarely covers the entire amount of potential damages. Insurers issue policies that employ deductibles, co-payments or their functional equivalents that require the insured to pay for some portion of the insured loss. Insurers do this to protect against the problem of "moral hazard," which arises when the behavior of the insured changes after insurance is obtained. In other words, to prevent the insured from assuming excessive risks, insurance policies require that the insured pay some portion of the loss.

Deductibles and their functional equivalents vary in amount, with deductibles for companies generally being larger than those for individuals. It is also common for larger companies to have larger deductibles than smaller companies. In addition, the *timing* of the deductible payment by the

insured varies. Some policies require the insured to pay for the loss up to the amount of the deductible *before* the insurer pays and some require the insured to reimburse the insurer *after* the insured makes the payment. Thus, the policy may allow or require the insured to pay for the entire damage amount and then the insurance company will reimburse the insured up to the policy limits minus the deductible.

A very small percentage of policies do not require the insured to pay any deductible or its equivalent and will cover losses without any contribution by the insured. Such "first-dollar" policies are often prohibitively expensive for companies, especially small technology companies like many in the medical device industry, because the insurer must be compensated for agreeing to ignore the moral hazard problem. Even in these first-dollar policies, however, the insurer rarely covers an infinite amount of potential losses. All policies of which we are aware in the medical device industry have a specified upper limit or cap on the amount that the insurer will pay for any given occurrence.

Automobile liability insurance is a good example of the way liability insurance works in practice—and it is also the quintessential type of insurance that the MSP was meant to reach. When an individual or a company's employee covered by an automobile policy gets into an accident, the insurance company will cover damages up to a certain pre-determined amount and the insured must pay a deductible portion of those damages, typically in the range of $100 to $500 per accident. The policy may require the insured to pay that amount upfront or it may collect the deductible amount after the insurance company has paid. Some large companies with large fleets of vehicles choose to self-insure rather than to pay some other entity to insure them. To do so, state laws require them to have administrative procedures in place for processing claims and to keep deposits or have other financial arrangements that will cover potential losses. See, *e.g.*, Del. Code Ann. tit. 21, § 2904.

Sensibly understood, therefore, the term "self-insured plan" reaches only large entities that seek to save on insurance costs by performing themselves the same risk-spreading and risk-management functions that private insurers perform. Rather than accept this commonsense meaning, the court below engaged in intellectual gymnastics to hold that the payment of a deductible, even in the absence of a plan to set aside monies for eventual liabilities, transformed petitioners from insureds to operators of "self-insured plans" because the deductibles required petitioners to cover some of the risk of loss. The Second Circuit rejected a similar argument precisely because of its sweeping and implausible implications. Such an interpretation "turns *every* corporation into an insurance company subject to suit under the MSP statute." *Mason*, 346 F.3d at 40.

> "Its logical implication is that any [corporate] entity with a risk of legal liability which chooses to retain any portion of that risk, no matter how small, may be pursued under MSP on the ground that it is a 'self-insured plan.' . . . The practical effects of [this] conception of MSP liability would transform the statute, meant primarily for use against insurers, *see Philip Morris [I]*, 116 F. Supp. 2d at 146 n. 22, into the very 'across-the-board procedural vehicle for suing tortfeasors,' which this Court has already declared impermissible. *Id.* at 135."

Id. (alterations and omission in original) (quoting *United States* v. *Philip Morris, Inc.*, 156 F. Supp. 2d 1, 7-8 (D.D.C. 2001)).

The Eleventh Circuit's holding admits of no rational limiting principles. *All* tortfeasors who have purchased insurance will be considered "self-insured plans" because they, like petitioners here, cover some of their risk of liability through either deductibles or caps on insurance coverage or both. Perhaps more disturbing is the fact that an insured with *any* deductible, no matter how small, would be subjected to

the government's collection practices for the entire amount of the Medicare expenditure, not just up to the amount of the deductible.

The second half of the Eleventh Circuit's holding—that petitioners "received payment" from a "primary plan" because their liability policies may have *reimbursed* petitioners rather than paying into the settlement fund directly—elevates form over substance and produces a nonsensical result that is inconsistent with the MSP and reality. As discussed above, liability insurers may pay for a loss either by paying the injured party directly or by reimbursing the insured after the insured has paid the injured party. In either case, it is the insurer, not the insured, that effectively pays the injured party. The payments may pass through the insured to the injured party and the fact that the insured "retains" the payment is an issue only of the timing of that payment. To leave the Eleventh Circuit's holding intact would, for no apparent reason in the statute, capture those entities whose insurers pay after settlement rather than before.

III. THE DECISION BELOW WILL UPSET PREVIOUS SETTLEMENTS, DISCOURAGE FUTURE SETTLEMENTS AND IMPOSE SIGNIFICANT COSTS ON SOCIETY.

The Eleventh Circuit has permitted the government to evade its statutory obligation to seek reimbursement of payments made to class plaintiffs who are also Medicare beneficiaries. Rather than intercept payments made from the settlement fund, the government waited over four years after settlement to seek reimbursement from petitioners outside of, and in addition to, the settlement funds already paid.

By reading the statute to allow the government to seek reimbursement from tortfeasors long after settlement has been entered, the Eleventh Circuit has injected uncertainty into the settlement process that will upset expectations based on settlements that have already occurred and will complicate

future settlements in a manner that Congress could not have intended. Innovators in general, and AdvaMed's members in particular, face the possibility of litigation over the use of their products as a regular part of their business. Settling such litigation is an efficient way to bring certainty and finality to the injured plaintiffs and to the defendants. The Eleventh Circuit's holding drastically reduces this certainty and eliminates closure associated with settlement because the government may or may not later seek additional damages directly from the tortfeasor above and beyond the amount paid in the settlement.

These concerns are particularly acute in many class action lawsuits where the exposure is large and settlements are sometimes structured mainly to compensate plaintiffs for their economic damages. For medical injuries, healthcare costs represent about one-half of total economic losses. E.J. Thomas et al., *Costs of Medical Injuries in Utah and Colorado*, 36 Inquiry 255 (1999). Accordingly, reimbursement sought by the government against alleged tortfeasors after doubling under the MSP can constitute a significant percentage of the total amount of a settlement fund created for the plaintiffs. To subject past settlements to such unexpected additional liability is profoundly unfair. Under the Eleventh Circuit's ruling, the government will be free to reopen numerous medical device liability cases AdvaMed's members had settled in good faith believing that the litigation and liability would come to an end.

On a prospective basis, the risks of such increased liability can only complicate and hinder the already difficult process of resolving mass tort claims. There are, for example, a number of pending medical device liability cases that have been consolidated by the Judicial Panel on Multidistrict Litigation and each involves a multitude of claims that might subject the parties to the uncertainty created by the Eleventh Circuit's novel holding. See, *e.g.*, *In re St. Jude Med., Inc., Silzone Heart Valves Prods. Liability Litig.*, No. MDL-1396,

No. 01-md-1396(JRT) (D. Minn. transferred Apr. 18, 2001); *In re Sulzer Orthopedics, Inc., Hip Prosthesis & Knee Prosthesis Prods. Liability Litig.*, No. MDL-1401, No. 01-cv-9000 (N.D. Ohio transferred June 19, 2001). Because mass tort litigation "clogs dockets for decades, creating burdens on the judicial system and delaying relief for injured parties[,] . . . . the general policy of federal courts to promote settlement before trial is even stronger in the context of large-scale class actions." *Icicle Seafoods, Inc.* v. *Baker (In re Exxon Valdez)*, 229 F.3d 790, 795 (9th Cir. 2000); see also *Isby* v. *Bayh*, 75 F.3d 1191, 1196 (7th Cir. 1996) ("Federal courts naturally favor the settlement of class action litigation."); *Franklin* v. *Kaypro Corp.*, 884 F.2d 1222, 1229 (9th Cir. 1989) ("'[I]t hardly seems necessary to point out that there is an overriding public interest in settling and quieting litigation. This is particularly true in class action suits. . . .'"). By creating such a strong disincentive to settle, the Eleventh Circuit, in the absence of any Congressional direction to do so and in contravention of judicial policy, read too much into the MSP.

Perhaps more importantly from a societal standpoint, the decision will have a detrimental impact on the number of new medical devices that reach patients who need them. Because the government's recoveries under the court's decision increase the amount of expected loss from injuries beyond the cost of actual injuries, innovators will be less inclined to place products on the market. As the marginal cost of placing the technology on the market exceeds the marginal benefit the innovator expects to recoup from its investment, the innovator will expect a net loss on the sale of the product. Technologies that are beneficial but only marginally profitable will be especially affected by the lower court's mistaken ruling.

IV. THE SUBSEQUENT AMENDMENT OF THE MSP DOES NOT UNDERMINE THE IMPORTANCE OF THE ELEVENTH CIRCUIT'S RULING.

Petitioners have explained that, even if the MSP's recently amended definition of "primary plan" is understood as a retroactive codification of the lower court's interpretation of "self-insured plan," the circuit split that the decision below creates will continue to affect thousands of entities and individuals who have allegedly violated their payment obligations to the government. Pet. 26-30. We note that there is an alternative, and more limited, interpretation of the amended definition that likewise would not eliminate the far-reaching impact of the Eleventh Circuit's holding that insured tortfeasors whose policies include deductibles are not "self-insured plans."

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), Pub. L. No. 108-173, 117 Stat. 2066, amended the definition of "primary plan" by adding the following clause:

> "An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance or otherwise) in whole or in part."

Id. § 301(b)(1), sec. 1862(b)(2), 117 Stat. at 2222. Notably, this language does *not* refer to entities that purchase insurance policies *with deductibles*. To the contrary, it focuses on those who *fail* to purchase insurance.

As AdvaMed has explained, permitting the government to seek Medicare reimbursement from insured tortfeasors whose policies include deductibles is an extraordinary—indeed, startling—legal weapon. Because Congress is not expected to "hide elephants in mouseholes," *Whitman* v. *American Trucking Ass'ns*, 531 U.S. 457, 468 (2001), it must express its intent to adopt extraordinary measures in clear and unambiguous terms. *MCI Telecomms. Corp.* v. *AT&T Co.*,

512 U.S. 218, 231 (1994). Congress could have easily expressed an intent to ratify the decision below, simply by referring to entities that carry risk "by failing to purchase insurance or by purchasing insurance policies with deductibles or their functional equivalents," yet it failed to do so. Accordingly, the amended definition of "primary plan" should not be understood to embrace insured tortfeasors whose policies include deductibles unless that is the only meaning the language can bear.

In fact, the amended language is susceptible of another, entirely plausible meaning. As noted, the statutory language itself focuses on an entity that carries its own risk by virtue of "a *failure* to obtain insurance." The language thus appears to be directed at situations where the government seeks reimbursement from someone who has no insurance. Although the statute refers to entities that carry their own risk "whether by a failure to obtain insurance *or otherwise*," the "or otherwise" clause is most plausibly understood to refer to actions (or inactions) that are comparable to a failure to purchase insurance, such as the failure to pay premiums that results in a lapse of coverage. See, *e.g.*, *Jarecki* v. *G.D. Searle & Co.*, 367 U.S. 303, 307 (1961) (the maxim that "a word is known by the company it keeps, while not an inescapable rule, is often wisely applied where a word is capable of many meanings in order to avoid the giving of unintended breadth to the Acts of Congress"). Similarly, the reference to carrying risk "in whole *or in part*" does not inescapably refer to carrying risk through deductibles; it can also refer to coverage that is partial in a temporal sense, because, for example, an insured allowed coverage to lapse and thus was covered only for part of a relevant time period. This alternative interpretation is plainly to be preferred over one in which the opaque phrases "or otherwise" and "in part" work a sea-change in the commonsense and widespread understanding that entities that purchase liability coverage from insurance companies are not self-insurers simply

because their policies have deductibles. See *MCI Telecomms. Corp.*, 512 U.S. at 231 (Congress does not effectuate sweeping, industry-wide changes through "such a subtle device").

Under this alternative interpretation, Congress has not repudiated or otherwise undermined the Second Circuit's conclusion in *Mason* that the mere retention of some portion of liability risk does not constitute a form of "self-insurance." Similarly, this alternative interpretation does not create the impediments to settlement and the disincentives to innovation that the Eleventh Circuit's breathtaking interpretation of the MSP creates. Accordingly, the amended definition of "primary plan" does not undermine the continued importance of the lower court's erroneous ruling, or the need for this Court's review. To the contrary, under this alternative interpretation of the amended definition, the decision below continues to present an issue of great importance not only for insured manufacturers of medical devices, but literally for every business or individual that purchases insurance policies with deductibles.

CONCLUSION

For the foregoing reasons, *amicus curiae* respectfully ask this Court to grant the petition for a writ of certiorari to the United States Court of Appeals for the Eleventh Circuit.

Respectfully submitted,

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